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FEDERAL REGISTER

Vol. 78 Wednesday,
No. 11 January 16, 2013

Pages 3311–3826

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

Contents

Federal Register

Vol. 78, No. 11

Wednesday, January 16, 2013

Agriculture Department
See Food and Nutrition Service

Alcohol and Tobacco Tax and Trade Bureau
PROPOSED RULES
Establishment of the Ballard Canyon Viticultural Area, 3370–3377

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3429–3431

Children and Families Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Mother and Infant Home Visiting Program Evaluation; Follow-up Data Collection on Family Outcomes, 3432–3433
School Readiness Goals and Head Start Program Functioning, 3431–3432

Coast Guard
RULES
Safety Zones:
Lower Portion of Anchorage #9, Mantua Creek Anchorage, Paulsboro, NJ , 3326–3328

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Financial Education Content Needs Survey, 3403–3407

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3407–3408

Defense Department
See Navy Department
RULES
Appointing Authority for Military Commissions, 3325–3326
NOTICES
Meetings:
U.S. Court of Appeals for Armed Forces Code Committee, 3408

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Client Assistance Program, 3409–3410
Form for Maintenance of Effort Waiver Requests under Elementary and Secondary Education Act of 1965, as Amended, 3410–3411
Formula Grant for Electronic Application System for Indian Education, 3411

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Meetings:
President's Council of Advisors on Science and Technology; Open Teleconference; Correction, 3411–3412

Environmental Protection Agency
RULES
Pesticide Tolerances:
Fluroxypyr, 3328–3333
Spiromesifen, 3333–3337
PROPOSED RULES
Pesticide Petitions:
Residues of Pesticide Chemicals in or on Various Commodities, 3377–3381
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
NSPS for Hospital/Medical/Infectious Waste Incinerators, 3414–3415
NSPS for Surface Coating of Plastic Parts for Business Machines, 3413–3414
Applications for Emergency Exemptions:
3–Decen–2–One, 3415–3417
Cancellations Orders for Pesticide Registrations and Labels:
Iodomethane, 3417–3418
Draft Guidance for Pesticide Registrants on Web-Distributed Labeling for Pesticide Products, 3418–3420
Draft Quality Standard for Environmental Data Collection, Production, and Use:
Non-EPA (External) Organizations and Two Associated QA Handbooks; Correction, 3420
Pesticide Emergency Exemptions:
Agency Decisions and State and Federal Agency Crisis Declarations, 3420–3422
Pesticide Products; Registration Applications, 3422–3423

Export-Import Bank
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Long Term Loan or Guarantee , 3423–3424

Federal Aviation Administration
RULES
Safety Enhancements, Certification of Airports, 3311–3317
PROPOSED RULES
Airworthiness Directives:
The Boeing Company Airplanes, 3363–3367
Various Aircraft Equipped with Wing Lift Struts, 3356–3363

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 3412

Initial Market-Based Rate Filings Including Requests for Blanket Authorizations:
EnerPenn USA LLC, 3412–3413
Texpo Power, LP, 3413
Meetings:
Federal Energy Regulatory Commission, 3413

Federal Maritime Commission
NOTICES
Agreements Filed, 3424
Ocean Transportation Intermediary License Applicants, 3424
Ocean Transportation Intermediary Licenses:
Rescission of Order of Revocation, 3424
Revocations, 3425

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 3425
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 3425

Federal Trade Commission
NOTICES
Proposed Consent Orders:
Filiquarian Publishing, LLC; Choice Level, LLC; and Joshua Linsk, 3425–3427
Motorola Mobility LLC and Google Inc.; Correction, 3427–3429

Fish and Wildlife Service
NOTICES
Meetings:
Migratory Bird Hunting; Service Regulations Committee, 3446

Food and Drug Administration
PROPOSED RULES
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 3646–3824
Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations:
Activities (Outside the Farm Definition) Conducted in Facility Co-Located on a Farm, 3824–3826
Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 3504–3646
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Electronic Submission of Adverse Event Reports and Other Safety Information Using Electronic Submission Gateway and Safety Reporting Portal, 3433–3437

Food and Nutrition Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Performance Reporting System, Management Evaluation, 3394–3396
Senior Farmers' Market Nutrition Program, 3393–3394
Supplemental Nutrition Assistance Program Employment and Training Program Activity Report, 3391–3393
Worksheet for Supplemental Nutrition Assistance Program Quality Control Reviews, 3390–3391

Foreign Claims Settlement Commission
NOTICES
Meetings; Sunshine Act, 3450

Health and Human Services Department
See Centers for Disease Control and Prevention
See Children and Families Administration
See Food and Drug Administration
See National Institutes of Health

Homeland Security Department
See Coast Guard
NOTICES
Privacy Act; Systems of Records, 3441–3446

Industry and Security Bureau
RULES
Entity List:
Removal of Persons Based on Request; Implementation of Annual Review Changes and Modifications and Corrections, 3317–3319
Validated End User Authorizations:
Advanced Micro Devices China, Inc., et al., in the People's Republic of China; Clarification of Scope of Entries in Supplement, 3319–3325

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Ocean Energy Management Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
RULES
Disclosure or Use of Information by Preparers of Returns; Correction, 3325
Partners Distributive Share; Correction, 3325
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3498–3499
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Customer Satisfaction Surveys, 3499
Meetings:
Taxpayer Advocacy Panel Joint Committee, 3500–3501
Taxpayer Advocacy Panel Notices and Correspondence Project Committee, 3500
Taxpayer Advocacy Panel Tax Forms and Publications Project Committee, 3501
Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee, 3500
Taxpayer Advocacy Panel Taxpayer Communications Project Committee, 3501
Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee, 3500

International Trade Administration
PROPOSED RULES
Extension of Time Limits, 3367–3370
NOTICES
Antidumping Duty Administrative Reviews; Results, Extensions, Amendments, etc.:
Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from People's Republic of China, 3396–3398
Meetings:
United States Travel and Tourism Advisory Board, 3398

International Trade Commission
NOTICES
Investigations:
Certain Microprocessors, Components Thereof, and Products Containing Same; Statements on Public Interest, 3449–3450
Silica Bricks and Shapes from China; Determination, 3449

Justice Department
See Foreign Claims Settlement Commission
See National Institute of Corrections

Land Management Bureau
NOTICES
Meetings:
Western Montana Resource Advisory Council, 3446–3447

National Capital Planning Commission
NOTICES
Meetings:
Comprehensive Plan for National Capital; Federal Elements, 3453

National Highway Traffic Safety Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3496–3497

National Institute of Corrections
NOTICES
Solicitations for Cooperative Agreements:
Development of Materials Specific to Lesbian, Gay, Bisexual, Transgender and Intersex Offenders in Corrections, 3450–3453

National Institutes of Health
NOTICES
Government-Owned Inventions; Availabilities for Licensing, 3437–3441

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Northeastern United States:
Atlantic Mackerel, Squid, and Butterfish Fisheries; Specifications and Management Measures, 3346–3355
High Seas Driftnet Fishing Moratorium Protection Act:
Identification and Certification Procedures to Address Shark Conservation, 3338–3346
PROPOSED RULES
Endangered and Threatened Species:
Designation of a Nonessential Experimental Population of Spring-run Chinook Salmon, San Joaquin River, CA, 3381–3389
NOTICES
Calls for Nominations:
International Pacific Halibut Commission Appointments, 3399
Draft 2012 Marine Mammal Stock Assessment Reports, 3399–3401
Fisheries of the Northeastern United States:
Atlantic Mackerel, Squid, and Butterfish Fisheries; Scoping Process, 3401–3402
Meetings:
Marine Fisheries Advisory Committee, 3402
Permits:
Marine Mammals; File No. 16919, 3402–3403

National Science Foundation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3453–3454

Navy Department
NOTICES
Environmental Impact Statements; Availability, etc.:
Gulf of Alaska Navy Training Activities, 3408–3409
Meetings:
Board of Visitors of Marine Corps University, 3409

Nuclear Regulatory Commission
NOTICES
Docketing of Amendment Requests to Special Nuclear Materials:
Independent Spent Fuel Storage Installation; License No. 2506, 3454–3458
Environmental Assessments; Availability, etc.:
Florida Power Corp., Crystal River Unit 3; Proposed License Amendment to Increase Maximum Reactor Power Level, 3458–3470
Environmental Impact Statements; Availability, etc.:
DTE Electric Co.; Combined License for Unit 3 at Enrico Fermi Atomic Power Plant Site, 3470
Hearings and to Petitions for Leave to Intervene:
Aptuit, LLC; License Amendment Request, Opportunity to Provide Comments, 3470–3473
Meetings:
Advisory Committee on Reactor Safeguards, 3473–3474
Advisory Committee on Reactor Safeguards Subcommittee on Materials, Metallurgy and Reactor Fuels, 3474

Ocean Energy Management Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Southern Alaska Sharing Network and Subsistence Study, 3447–3448

Personnel Management Office
NOTICES
Privacy Act; Computer Matching Programs, 3474–3476

Postal Regulatory Commission
NOTICES
International Mail Contracts, 3476–3479

Presidio Trust
NOTICES
Meetings:
Fort Scott Council, 3479

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
BATS Exchange, Inc., 3489–3494
Chicago Board Options Exchange, Inc., 3486–3489
Chicago Stock Exchange, Inc., 3485–3486
NASDAQ Stock Market LLC, 3480–3482, 3485
NYSE Arca, Inc., 3482
Options Clearing Corp., 3479, 3483–3485
Stock Clearing Corp. of Philadelphia, 3482

Small Business Administration
NOTICES
Disaster Declarations:
Mississippi, 3494–3495

Puerto Rico, 3495
Exemptions under Small Business Investment Act; Conflicts of Interest:
Claritas Capital Specialty Debt II, LP, 3495
Major Disaster Declarations:
Maryland; Amendment 3, 3496
Surrenders of Licenses of Small Business Investment Companies, 3496

State Department
NOTICES
Specially Designated Global Terrorists:
Michel Samaha, a.k.a. Saadah al–Naib Mishal Fuad Samahah, a.k.a. Mishal Fuad Samahah, 3496

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 3448–3449

Surface Transportation Board
NOTICES
Acquisitions and Operation Exemptions:
KM Railways, LLC from DTE Chicago Fuels Terminal, LLC and DTE Coal Services, Inc., 3497–3498

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration
See Surface Transportation Board

Treasury Department
See Alcohol and Tobacco Tax and Trade Bureau
See Internal Revenue Service
NOTICES
Meetings:
Debt Management Advisory Committee, 3498

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 3504–3826

Reader Aids
Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

14 CFR
139 3311
Proposed Rules:
39 (3 documents) ... 3356, 3363, 3365

15 CFR
744 3317
748 3319

19 CFR
Proposed Rules:
351 3367

21 CFR
Proposed Rules:
1 3646
16 (2 documents) 3504, 3646
106 3646
110 3646
112 3504
114 3646
117 (2 documents) 3646, 3824
120 3646
123 3646
129 3646
179 3646
211 3646

26 CFR
1 (2 documents) 3325

27 CFR
Proposed Rules:
9 3370

32 CFR
18 3325

33 CFR
165 3326

40 CFR
180 (2 documents) 3328, 3333
Proposed Rules:
180 3377

50 CFR
300 3338
648 3346
Proposed Rules:
223 3381

Rules and Regulations

Federal Register

Vol. 78, No. 11

Wednesday, January 16, 2013

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 139

[Docket No.: FAA–2010–0247; Amdt. No. 139–27]

RIN 2120–AJ70

Safety Enhancements, Certification of Airports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rulemaking amends regulations pertaining to certification of airports to clarify that the applicability of these regulations is based only on passenger seats in passenger-carrying operations as determined by either the regulations or the aircraft type certificate. This final rule also adds a new section that prohibits fraudulent or intentionally false statements concerning an airport operating certificate. Finally, this final rule adopts administrative changes for internal consistency, or to codify existing industry practice. These changes are necessary to clarify the applicability language, and ensure the reliability of records maintained by a certificate holder and reviewed by the FAA. Lastly, this final rule changes the definition of joint-use airport to correspond with statutory authority.

DATES: Effective March 18, 2013.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How To Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Kenneth Langert, Office of Airports Safety and Standards, Airport Safety and Operations Division (AAS–300), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 493–4529; e-mail *Kenneth.Langert@faa.gov.* For legal questions concerning this action, contact Sabrina Jawed, AGC–240, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3073; fax (202) 267–7971; email *Sabrina.Jawed@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart III, section 44706, ''Airport Operating Certificates''. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce, including issuing airport operating certificates that contain terms the Administrator finds necessary to ensure safety in air transportation. This regulation is within the scope of that authority because it would (i) enhance safety in airport operations by clarifying the applicability of part 139, and (ii) explicitly prohibit fraudulent or intentionally false statements in a certificate application or record required to be maintained by the certificate holder.

I. Overview of Final Rule

This final rule will:

- Clarify that the applicability of part 139 is based only on passenger seats in passenger-carrying operations, as determined by either the regulations or the aircraft type certificate (§ 139.1);
- Add a new § 139.115 that prohibits fraudulent or intentionally false statements concerning an airport operating certificate (AOC);
- Amend language in § 139.303 and § 139.329 for consistency, or to codify existing industry practice; and
- Amend the definition of joint-use airport in § 139.5 to correspond with statutory authority.

II. Summary of the Costs and Benefits of the Final Rule

Although the FAA cannot quantify the benefits of this final rule, the FAA believes that the benefits will exceed the minimal unquantifiable costs imposed by this final rule because this final rule will provide consistent rule language and accurate reporting.

III. Background

A. Summary of NPRM

Part 139 prescribes the minimum standards for maintaining and operating the physical airport environment. The FAA issues AOCs under part 139 to certain airports serving commercial passenger-carrying operations based on the type of commercial operations and size of aircraft served. As of December 31, 2012, 544 of the four classes of airports (I, II, III, and IV) defined in part 139 hold FAA-issued AOCs.

On February 1, 2011, the FAA published a notice of proposed rulemaking (NPRM) on Safety Enhancements Part 139, Certification of Airports (76 FR 5510). In the NPRM, the FAA proposed to amend the airport certification standards in part 139 by:

(1) Clarifying the applicability of part 139,

(2) Explicitly prohibiting fraudulent or intentionally false statements in a certificate application or record required to be maintained,

(3) Requiring a Surface Movement Guidance Control System (SMGCS) plan if the certificate holder conducts low-visibility operations,

(4) Establishing minimum standards for training of personnel who access the airport non-movement area, and

(5) Requiring certificate holders to conduct pavement surface evaluations to ensure reliability of runway surfaces in wet weather conditions.

The comment period closed on April 4, 2011. On April 13, 2011, the FAA reopened the comment period until May 13, 2011, (76 FR 20570) because we learned that a number of airport operators were not aware that low-visibility approaches and departures had been approved for their airports. The FAA notified, by letter, those airports with approved low-visibility departures, and reopened the comment

period to allow time for affected airports to receive notice from the FAA, review this NPRM, and adequately assess, prepare, and submit comments on the possible impact of this NPRM.

On June 3, 2011, the FAA again reopened the comment period until July 5, 2011, (76 FR 32105) because several industry groups requested the full economic evaluation the FAA developed for this rule. The FAA posted the full economic evaluation in the docket to allow industry time to review it, and adequately assess, prepare, and submit comments on the possible impact of this NPRM.

B. Summary of Comments

The FAA received 49 comment documents in response to the NPRM from the following commenters: Alaska DOT &PF; American Association of Airport Executives (AAAE); Airports Council International—North America (ACI–NA); Air Line Pilots Association, International (ALPA); Aircraft Owners and Pilots Association (AOPA); Broward County Aviation Department; Burlington International Airport; City of Atlanta Department of Aviation; City of Prescott; Clark County Department of Aviation; Dallas/Fort Worth International Airport; Denver International Airport; Experimental Aircraft Association (EAA); Fairbanks International Airport; Glynn County Airport Commission; Houston Airport System; Ithaca Tompkins Regional Airport; Kent County Department of Aeronautics; Lafayette Airport Commission; Los Angeles World Airport; Louisville Regional Airport Authority; Manchester-Boston Regional Airport; Maryland Aviation Administration; Mid Ohio Valley Airport; Municipal Airport Authority of the City of Fargo; Myrtle Beach International Airport; National Air Transportation Association (NATA); Omni Air International; Phoenix Sky Harbor International Airport; Port of Seattle; Portland International Airport; Rapid City Regional Airport; Salt Lake City International; Sarasota Manatee Airport Authority; Sioux Falls Regional Airport; Southwest Airlines; St. Petersburg-Clearwater International Airport; The Columbus Regional Airport Authority; The Port Authority of New York & New Jersey; Western Reserve Port Authority; and nine individuals. All of the commenters generally recommended changes to the proposal.

C. Differences Between the NPRM and the Final Rule

The table below shows the main topics covered by the proposals in the NPRM (indicated by a ''YES'') and whether or not the proposal for that topic is in this final rule (indicated by either a ''YES'' or a ''NO'').

Safety enhancements part 139	NPRM	Final rule
Applicability of Part 139	YES ...	YES.
Certification and Falsification.	YES ...	YES.
Surface Movement Guidance Control System (SMGCS).	YES ...	NO.
Non-Movement Area Safety Training.	YES ...	NO.
Runway Pavement Surface Evaluation.	YES ...	NO.

In addition to the above, the FAA is adopting administrative changes and amending the definition of joint-use airport, as discussed below. The administrative changes will not require part 139 AOC holders to change their current operational practices.

IV. Discussion of Final Rule and Comments

A. Applicability of Part 139 (§ 139.1)

Currently, § 139.1(a)(1) states that an airport must be certificated under part 139 to host scheduled passenger carrying operations of an air carrier operating aircraft designed for more than nine passenger seats, as determined by the aircraft type certificate issued by a competent civil aviation authority. The current wording of § 139.1 has created confusion regarding the operation of a particular aircraft type, the Cessna 208B Caravan (the ''Caravan''). The standard high-density airline configuration for the Caravan features four rows of 1–2 seating behind the two seats in the cockpit. The Caravan is certificated as a single-pilot aircraft, but has two pilot seats. In non-revenue service, the second pilot seat may be occupied by a passenger. However, in scheduled passenger-carrying operations, § 135.113 prohibits passengers from occupying the second pilot seat, which means there are not more than nine passenger seats during those operations.

In the NPRM, the FAA proposed to clarify § 139.1 to state that the applicability of part 139 is based only on passenger seats in passenger-carrying operations as determined by either the regulations under which the operation is conducted or the aircraft type certificate.

No comments specifically objected to the proposal to clarify the applicability of part 139. The final rule adopts the language as proposed.

B. Certification and Falsification (§ 139.115)

The FAA proposed a new § 139.115 that would prohibit fraudulent or intentionally false statements on an application for a certificate or other records required to be kept.

All comments regarding this section supported the FAA's proposal. To ensure the reliability of records maintained by a certificate holder and reviewed by the FAA, the FAA is adding a new § 139.115 that prohibits:

(1) The making of any fraudulent or intentionally false statement on an application for a certificate;

(2) The making of any fraudulent or intentionally false statement on any record or report required by the FAA; and

(3) The reproduction or alteration, for a fraudulent purpose, of any FAA certificate or approval.

The final rule allows the FAA to suspend or revoke an AOC if an owner, operator, or other person acting on behalf of the certificate holder violates any of these prohibitions. The FAA may also suspend or revoke any other FAA certificate issued to the person committing the act. This requirement is similar to the falsification prohibitions in 14 CFR parts 43, 61, 65, and 67.

C. SMGCS (§ 139.203)

The FAA proposed to amend § 139.203 to require that airport certification manuals contain a SMGCS plan for airports approved for operations below 1,200 feet runway visual range. A SMGCS plan would facilitate the safe movement of aircraft and vehicles on the airport by establishing more rigorous control procedures and requiring enhanced visual aids. Additionally, the ability to conduct low visibility operations allows a certificate holder to stay open during poor weather conditions, thus reducing flight delays and cancellations.

The basis for approving low-visibility operations for each runway would be incorporated in the certificate holder's SMGCS plan. Only certificate holders that conduct low-visibility operations would be required to develop and implement a SMGCS plan. These plans would vary among airports because of local conditions, and would be subject to FAA approval.

Twelve commenters stated that either the cost calculations in our proposal were not realistic, or the amount of time in low-visibility conditions did not warrant the investment. Additionally, several comments contended that the burden to airports would not be beneficial, and would require a large

infrastructure investment. Based on comments and further cost analysis, this section of the rule is not currently cost beneficial to implement and the FAA is withdrawing the SMGCS proposal. However, the FAA may propose rulemaking in the future if it is determined to be necessary.

D. Training (§§ 139.303 & 139.329)

i. Non-Movement Area

In the NPRM, the FAA proposed to require training for all persons authorized to access the non-movement area (with certain exceptions noted in the proposal). This training would complement the existing training for persons accessing the movement and safety areas, and could be combined with the training for persons accessing both the movement and non-movement areas.

Nearly all commenters expressed support for increasing safety. However, most commenters contended the proposal was unnecessary because airlines and ground servicing providers conduct safety training to satisfy the Occupational Safety and Health Administration (OSHA) requirements. They also stated the cost to the industry would be burdensome, and would take away time from other duties that produce greater safety benefits. Further, they stated the NPRM overstates the benefit and underestimates the lifecycle costs by not including costs for additional staff or facilities needed for training and record keeping. One airport included a cost case study, and other airports provided differing cost figures that were helpful in identifying all costs involved.

Based on comments and further analysis, the FAA is withdrawing the proposal covering non-movement area safety training. However, the FAA may propose rulemaking in the future if it is determined to be necessary.

ii. Substituting ''Persons'' for ''Personnel''

The proposal also included substituting all ''persons'' for all ''personnel'' in § 139.303(c). We received no comments objecting to this change. The FAA adopts this change, and will also substitute all ''persons'' for ''employee, tenant or contractor'' in §§ 139.329 (b) and (e) for consistency. The FAA has determined this language provides greater clarity and is consistent with previous FAA interpretations.

iii. Annual Recurrent Training

Since 2007, the U.S. aviation community has initiated and completed significant short-term actions to improve safety at U.S. airports based on the FAA's ''Call to Action.'' [1] As part of the Call to Action, the FAA Office of Airport Safety and Standards issued a change to AC 150/5210–20, Ground Vehicle Operations on Airports, on March 31, 2008. The AC change strongly recommended regular recurrent driver training for all persons with access to the movement area. This included voluntarily conducting recurrent annual movement area driver's training for all personnel who enter the movement area. All certificated airports voluntarily developed plans to require annual recurrent training for all individuals with access to the movement areas. As a result of the Call to Action, in 2010 the Office of Airports recorded that all airports were requiring recurrent training for non-airport employees such as Fixed-Base Operators (FBO) or airline mechanics.[2] The FAA intended to propose a requirement in the NPRM that would make the existing industry practice mandatory. Given the universality of the training, the FAA has determined that it would be contrary to the public interest to initiate a separate rulemaking action just for this provision in order to provide an opportunity to comment. The existing level of training indicates that as a group certificated airports are willing to conduct the training, and that codifying existing industry practice adds no further costs.

This final rule now requires annual recurrent training for all persons in the movement and safety areas for Classes I through IV airports. Regulatory text is being added to § 139.329 to further clarify that all persons that have access to, and operate in, movement areas and safety areas require initial and recurrent drivers training (at least once every 12 consecutive calendar months). Additionally, since Class IV airports will be required to comply with this regulation, an ''X'' will be added in the Class IV column in § 139.203(b) manual element number 22.

E. Runway Pavement Surface Evaluation (§ 139.305)

In the NPRM, the FAA proposed amending § 139.305 to require airports to establish and implement a runway friction testing program for each runway used by jet aircraft. Under the proposal, a certificate holder would schedule periodic friction evaluations of each runway that accommodates jet aircraft. Components of the program would include a testing frequency that takes into consideration the volume and type of traffic as well as friction readings from continuous friction measuring equipment (CFME) operated by trained personnel. Corrective action would be required, as needed.

Ten commenters questioned whether the cost of the CFME or the tests required would provide significant benefit. Five commenters wanted to know who would be responsible for qualifying the trainers for the CFME operators. The remaining comments raised concerns about:

(i) Non-jet traffic;

(ii) The use of the CFME for winter operations;

(iii) What constitutes acceptable friction levels;

(iv) What is an acceptable testing frequency;

(v) Are there any funding sources;

(vi) What is the implementation time frame; and

(vii) Consideration of new equipment.

The FAA also proposed for § 139.305 that airport operators be required to locate potential hydroplaning areas as well as measure the depth and width of a runway's grooves to check for wear and damage. Airports would also establish and implement a program for testing performance of grooves and transverse slopes.

Four commenters stated that the NPRM did not provide enough detail for cross-slope inspection requirements. Three commenters felt that this issue was already considered in current part 139 regulations. Other commenters wanted the FAA to determine inspection specifics and acceptance levels. Two commenters thought that this proposal would increase costs.

Based on comments and further analysis, the FAA is withdrawing the proposals for § 139.305. The FAA notes that guidance currently exists addressing these issues and it will conduct outreach with certificate holders. Guidance on runway friction testing frequency and friction levels is in Advisory Circular 150/5320–12C Measurement, Construction, and Maintenance of Skid-Resistant Pavement Surfaces. Guidance on the use of CFME in contaminated conditions for operational purposes is found in Advisory Circular 150/5200–30C, Airport Winter Safety and Operations. Finally, the FAA notes that current part 139 requirements require airports to inspect runways for ponding problems. However, the FAA may propose rulemaking in the future if it is determined to be necessary.

[1] See FAA Fact Sheet at *www.faa.gov/news/fact_sheets/news_story.cfm?newsId=10133.*

[2] See FAA Annual Runway Safety Report 2010, at *www.faa.gov/airports/runway_safety/news/publications/media/Annual_Runway_Safety_Report_2010.pdf.*

F. Definition of Joint Use Airport (§ 139.5)

The FAA is changing the definition of ''joint use airport'' in § 139.5 to correspond with the definition provided by Congress in the FAA Modernization and Reform Act of 2012 (49 U.S.C. 47175 (2012)). This change is not subject to notice and comment procedures because it meets the Administrative Procedure Act's good cause exception (5 U.S.C. 553).

V. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

In conducting these analyses, the FAA has determined that this final rule:

(1) Imposes no incremental costs and provides benefits,

(2) Is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866,

(3) Is not significant as defined in DOT's Regulatory Policies and Procedures;

(4) Will not have a significant economic impact on a substantial number of small entities;

(5) Will not have a significant effect on international trade; and

(6) Will not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the monetary threshold identified.

These analyses are summarized below.

In response to public comments, the FAA is withdrawing some proposed NPRM requirements. This section analyzes the economic impacts of the provisions of this final rule.

This final rule will:

- Clarify that the applicability of part 139 is based only on passenger seats in passenger-carrying operations, as determined by the regulations or the aircraft type certificate (§ 139.1);
- Add a new § 139.115 that prohibits fraudulent or intentionally false statements concerning an AOC or other record required to be maintained;
- Amend language in §§ 139.303 and 138.329 for consistency or to codify current industry practice; and
- Amend the definition of joint-use airport in § 139.5 to correspond with statutory authority.

The benefits and costs of each of these sections of this final rule are discussed below.

i. Applicability of Part 139 (§ 139.1)

This section of this final rule clarifies that the applicability of part 139 is based only on passenger seats in passenger-carrying operations, as determined by the regulations or the aircraft type certificate.

No quantitative benefits or costs are estimated for this section of the final rule because it simply clarifies existing FAA requirements.

ii. Certification and Falsification (§ 139.115)

This section of this final rule is intended to ensure the reliability of records maintained by a certificate holder and reviewed by the FAA by specifically prohibiting fraudulent or intentionally false statements concerning an AOC or other record required to be maintained.

This section of this final rule has positive qualitative benefits because it emphasizes the importance of accurate reporting of airport data. However, no quantitative benefits are estimated for this section of this final rule.

There are no costs for this section of this final rule because it simply formalizes the keeping and reporting of accurate airport data.

This requirement is similar to the falsification prohibitions in 14 CFR parts 43, 61, 65, and 67.

iii. Amended Language in §§ 139.303 and 139.329

Currently, there are inconsistencies in the way people are referred to in these sections. This final rule will replace all references to people with the term persons. Additionally, the FAA will require annual recurrent training for all persons in the movement and safety areas and include Class IV airports to align with current industry practice.

The qualitative benefit of this portion of this final rule will be to provide consistent language within and between §§ 139.303 and 138.329. However, the FAA cannot provide a quantitative estimate of these benefits.

There are no costs for this portion of this final rule because this changed language is consistent with previous FAA interpretations.

Although the FAA cannot quantify the benefits of this final rule, the FAA believes that the benefits will exceed the minimal unquantifiable costs imposed by this final rule.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency

may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

i. Publicly Owned Airports

Size standards for small entities are published by the Small Business Administration (SBA). The small entity size standard for municipalities, including those owning publicly-owned airports, is a population less than 50,000 people.

The population of municipalities owning airports ranges from many millions to a few thousand. Many part 139 airport owners are small entities. Therefore, this final rule will affect a large number of small entities. However, this final rule will not have a significant economic impact on any small entity because the final rule imposes no incremental costs.

Therefore, as the acting FAA Administrator, I certify that this final rule will not have a significant economic impact on a substantial number of part 139 airport owners.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that it will have only a domestic impact and therefore will not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. In the NPRM, we provided data on the information collection requirements associated with the proposals in that document. However, the proposals that created these information collection requirements are not in this final rule. Therefore, the FAA has determined that there is no new requirement for information collection associated with this final rule.

F. International Compatibility and Cooperation

(1) In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

(2) Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

G. Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in Chapter 3, paragraph 312d, and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. Most airports subject to this rule are owned, operated, or regulated by a local government body (such as a city or county government), which, in turn, is incorporated by or is part of a State. Some airports are operated directly by a State.

This final rule, which modifies an existing regulatory requirement, imposes no incremental costs and would not alter the relationship between certificate holders and the FAA as established by law. This final rule is not a significant regulatory action under the Unfunded Mandates Reform Act of 1995. Accordingly, the FAA has determined that this action does not have a substantial direct effect on the States. This final rule makes administrative amendments to existing regulatory requirements for certificate holders. These requirements are under existing statutory authority to regulate airports for aviation safety. Accordingly, there is no change in either the relationship between the Federal Government and the Sates, or the distribution of power among the various levels of government.

The FAA mailed a copy of the NPRM to each State government specifically inviting comment on Federalism issues. No comments were received.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VII. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visit the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/;* or

3. Access the Government Printing Office's Web page at *http://www.gpo.gov/fdsys.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 139

Air carriers, Airports, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 139—CERTIFICATION OF AIRPORTS

■ 1. The authority citation for part 139 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44709, 44719.

■ 2. Amend § 139.1 by revising paragraph (a) to read as follows:

§ 139.1 Applicability.

(a) This part prescribes rules governing the certification and operation of airports in any State of the United States, the District of Columbia, or any territory or possession of the United States serving any—

(1) Scheduled passenger-carrying operations of an air carrier operating aircraft configured for more than 9 passenger seats, as determined by the regulations under which the operation is conducted or the aircraft type certificate issued by a competent civil aviation authority; and

(2) Unscheduled passenger-carrying operations of an air carrier operating aircraft configured for at least 31 passenger seats, as determined by the regulations under which the operation is conducted or the aircraft type certificate issued by a competent civil aviation authority.

* * * * *

■ 3. Amend § 139.5 to revise the definition of the term ''Joint-use airport'' to read as follows:

§ 139.5 Definitions.

* * * * *

Joint-use airport means an airport owned by the Department of Defense, at which both military and civilian aircraft make shared use of the airfield.

* * * * *

■ 4. Add § 139.115 to subpart B to read as follows:

§ 139.115 Falsification, reproduction, or alteration of applications, certificates, reports, or records.

(a) No person shall make or cause to be made:

(1) Any fraudulent or intentionally false statement on any application for a certificate or approval under this part.

(2) Any fraudulent or intentionally false entry in any record or report that is required to be made, kept, or used to show compliance with any requirement under this part.

(3) Any reproduction, for a fraudulent purpose, of any certificate or approval issued under this part.

(4) Any alteration, for a fraudulent purpose, of any certificate or approval issued under this part.

(b) The commission by any owner, operator, or other person acting on behalf of a certificate holder of an act prohibited under paragraph (a) of this section is a basis for suspending or revoking any certificate or approval issued under this part and held by that certificate holder and any other certificate issued under this title and held by the person committing the act.

■ 5. Amend § 139.203 by revising paragraph (b)(22) to read as follows:

§ 139.203 Contents of Airport Certification Manual.

* * * * *

(b) * * *

Manual elements	Airport certificate class			
	Class I	Class II	Class III	Class IV
* * * *	*		*	*
22. Procedures for controlling pedestrians and ground vehicles in movement areas and safety areas, as required under § 139.329	X	X	X	X
* * * *	*		*	*

■ 6. Amend § 139.303 by revising the introductory text of paragraph (c) to read as follows:

§ 139.303 Personnel.

* * * * *

(c) Train all persons who access movement areas and safety areas and perform duties in compliance with the requirements of the Airport Certification Manual and the requirements of this part. This training must be completed prior to the initial performance of such duties and at least once every 12 consecutive calendar months. The curriculum for initial and recurrent training must include at least the following areas:

* * * * *

■ 7. Amend § 139.329 by revising paragraph (b) and paragraph (e) to read as follows:

§ 139.329 Pedestrians and ground vehicles.

* * * * *

(b) Establish and implement procedures for the safe and orderly access to and operation in movement

areas and safety areas by pedestrians and ground vehicles, including provisions identifying the consequences of noncompliance with the procedures by all persons;

* * * * *

(e) Ensure that all persons are trained on procedures required under paragraph (b) of this section prior to the initial performance of such duties and at least once every 12 consecutive calendar months, including consequences of noncompliance, prior to moving on foot, or operating a ground vehicle, in movement areas or safety areas; and

* * * * *

Issued in Washington, DC, on January 4, 2013.

Michael P. Huerta,

Acting Administrator.

[FR Doc. 2013–00848 Filed 1–15–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 121113624–2624–01]

RIN 0694–AF82

Removal of Persons From the Entity List Based on Removal Request; Implementation of Entity List Annual Review Changes; and Implementation of Modifications and Corrections to the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by removing two persons from the Entity List (Supplement No. 4 to Part 744), as the result of a request for removal submitted by these two persons. In addition, on the basis of the annual review conducted by the End User Review Committee, this rule amends the Entity List to remove two entries from the United Arab Emirates (U.A.E.). Finally, this rule modifies two existing entries to correct the scope of those entries, including removing a redundant entry that was inadvertently added in a final rule.

DATES: *Effective Date:* This rule is effective January 16, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Nies-Vogel, Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Fax: (202) 482–3911, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List (Supplement No. 4 to Part 744) notifies the public about entities that have engaged in activities that could result in an increased risk of the diversion of exported, reexported, or transferred (in-country) items to weapons of mass destruction (WMD) programs. Since its initial publication, grounds for inclusion on the Entity List have expanded to activities sanctioned by the State Department and activities contrary to U.S. national security or foreign policy interests, including terrorism and export control violations involving abuse of human rights. Certain exports, reexports, and transfers (in-country) to entities identified on the Entity List require licenses from BIS and are usually subject to a policy of denial. The availability of license exceptions in such transactions is very limited. The license review policy for each entity is identified in the License Review Policy column on the Entity List and the availability of license exceptions is published in the **Federal Register** notices adding persons to the Entity List. BIS places entities on the Entity List based on certain sections of part 744 (Control Policy: End-User and End-Use Based) of the EAR.

The End-user Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Removal From the Entity List

This rule implements a decision of the ERC to remove two persons, Laurence Mattiucci and Toulouse Air Spares SAS, both located in France, from the Entity List as a result of a successful request for removal from the Entity List. Based upon the review of the information provided in the removal request in accordance with § 744.16 (Procedure for requesting removal or modification of an Entity List entity), and after review by the ERC's member agencies, the ERC determined that these persons should be removed from the Entity List.

The ERC's decision to remove these two persons took into account their cooperation with the U.S. Government, as well as their assurances of future compliance with the EAR. In accordance with § 744.16(c), the Deputy Assistant Secretary for Export Administration has sent written notification to these two persons, informing these entities of the ERC's decision to remove them from the Entity List. This final rule implements the decision to remove the following two persons from the Entity List:

France

(1) *Laurence Mattiucci,* 8 Rue de la Bruyere, 31120 Pinsaguel, Toulouse, France; *and*

(2) *Toulouse Air Spares SAS,* 8 Rue de la Bruyere, 31120 Pinsaguel, Toulouse, France.

Annual Review of the Entity List

This rule also amends the Entity List on the basis of the annual review of the Entity List conducted by the ERC, in accordance with the procedures outlined in Supplement No. 5 to part 744 (Procedures for End-User Review Committee Entity List Decisions). The changes from the annual review of the Entity List that are approved by the ERC are implemented in stages as the ERC completes its review of entities listed under different destinations on the Entity List. This rule implements the results of the annual review for entities located in the United Arab Emirates (U.A.E.). The entities located Armenia, Cyprus, France, and Iran were also reviewed by the ERC, but no additional changes are being made to those entries as a result of the annual review of the Entity List.

Removals From the Entity List on the Basis of Annual Reviews

This rule removes two entries from the Entity List on the basis of the annual review of the Entity List. The persons removed were determined to no longer meet the criteria for inclusion on the Entity List. Specifically, this rule implements the decision of the ERC to remove two persons located in the U.A.E., as follows:

United Arab Emirates

(1) *Abubakr Abuelazm,* Dubai, U.A.E., 500100; *and*

(1) *Advanced Technology General Trading Company,* a.k.a, Advanced Technologies Emirates FZ–LLC, Office #124 1st Floor, Building #3, Dell Building, Sheikh Zayed Road, Dubai Internet City, Dubai, U.A.E.

The removal of the above-referenced two entities on the basis of annual review of the Entity List, and the removal of the two entities referenced

above on the basis of a § 744.16 removal request that was approved by the ERC, eliminates the existing license requirements in Supplement No. 4 to part 744 for exports, reexports, and transfers (in-country) to these four entities. However, the removal of these four entities from the Entity List does not relieve persons of other obligations under part 744 of the EAR or under other parts of the EAR. Neither the removal of an entity from the Entity List nor the removal of Entity List-based license requirements relieves persons of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that, ''you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR.'' Additionally, these removals do not relieve persons of their obligation to apply for export, reexport, or in-country transfer licenses required by other provisions of the EAR. BIS strongly urges the use of Supplement No. 3 to part 732 of the EAR, ''BIS's 'Know Your Customer' Guidance and Red Flags,'' when persons are involved in transactions that are subject to the EAR.

Modifications and Corrections to the Entity List

On October 9, 2012, BIS published a final rule, ''Addition of Certain Persons to the Entity List'' in the **Federal Register** (77 FR 61249). This rule amends the Entity List by revising one entry added on October 9 under Finland and by removing one redundant entry under Russia. Specifically, the spelling of the ''Olkerboy Oy'' entry under Finland is corrected to ''Olkebor Oy'' and the ''Bolshaya Semenovskaya'' entry under Russia is removed. This rule revises the Olkerboy Oy entry under Finland, as follows:

Finland

(1) *Olkebor Oy/Nurminen Oy,* 231B Vanha Porvoontie, Vantaa, Finland 01380.

This rule also removes the Bolshaya Semenovskaya entry under Russia:

Russia

(1) *Bolshaya Semenovskaya* 40/505, Moscow, Russia 107023; *and* Ulitsa Metallurgov, 29, Str. 1, Komnata Pravleni, Moscow, Russia 111401.

Savings Clause

Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on January 16, 2013, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 15, 2012, 77 FR 49699 (August 16, 2012), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by the OMB under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 43.8 minutes for a manual or electronic submission. This rule does not alter any information collection requirements; therefore, total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and a 30-day delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). The U.S. Government's original basis for adding the entities affected by this rule to the Entity List was the entities' involvement in activities contrary to U.S. national security or foreign policy interests. BIS implements this rule to further protect U.S. national security and foreign policy interests by preventing items from being exported, reexported or transferred (in-country) to these persons listed on the Entity List and by ensuring that potential transactions with individuals no longer listed on the Entity List are not turned away to the detriment of U.S. economic interests. If this rule were delayed to allow for notice and comment and a 30-day delay in effective date, there is a chance that certain exporters, reexporters, and persons making transfers (in-country) to this listed person may inadvertently export, reexport or transfer (in-country) to *Olkebor Oy/Nurminen Oy* because the exporter, reexporter or person making the transfer (in-country) did not realize the listed person was subject to the Entity List-based license requirement. There is also a chance an exporter, reexporter, or person making a transfer (in-country) may turn away a potential export, reexport, or transfer (in-country) because the customer remained a listed person on the Entity List after the ERC approved removal, thereby harming U.S. economic interests. The correction and removals provided in this rule may make clear that the persons are no longer subject to Entity List-based license requirements. For these reasons, there is a public interest that these changes be implemented as a final action. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22

U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 19, 2012, 77 FR 3067 (January 20, 2012) Notice of August 15, 2012, 77 FR 49699 (August 16, 2012); Notice of September 11, 2012, 77 FR 56519 (September, 12, 2012); Notice of November 1, 2012, 77 FR 66513 (November 5, 2012).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. By removing under Finland the Finnish entity ''Olkerboy Oy/Nurminen Oy'', and adding in alphabetical order, one Finnish entity for Olkebor Oy/Nurminen Oy'';

■ b. By removing under France, the two French entities: ''Laurence Mattiucci, 8 Rue de la Bruyere, 31120 Pinsaguel, Toulouse, France.'' and ''Toulouse Air Spares SAS, 8 Rue de la Bruyere, 31120 Pinsaguel, Toulouse, France.'';

■ c. By removing under Russia, the Russian entity: ''Bolshaya Semenovskaya, 40/505, Moscow, Russia 107023; and Ulitsa Metallurgov, 29, Str. 1, Komnata Pravleni, Moscow, Russia 111401.''; and

■ d. By removing under United Arab Emirates, the two Emirati entities: ''Abubakr Abuelazm, Dubai, U.A.E., 500100.'' and ''Advanced Technology General Trading Company, a.k.a, Advanced Technologies Emirates FZ–LLC, Office #124 1st Floor, Building #3, Dell Building, Sheikh Zayed Road, Dubai Internet City, Dubai, U.A.E.''

The addition reads as follows:

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	*	*	*	*
FINLAND				
*	*	*	*	*
	Olkebor Oy/Nurminen Oy, 231B Vanha Porvoontie, Vantaa, Finland 01380.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	77 FR 61256, 10/9/2012. 78 FR [INSERT FR PAGE NUMBER] 1/16/13.
*	*	*	*	*

Dated: January 10, 2013.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2013–00767 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 121220730–2730–01]

RIN 0694–AF84

Amendments to Existing Validated End User Authorizations: Advanced Micro Devices China, Inc., Lam Research Corporation, SK hynix Semiconductor (China) Ltd., and SK hynix Semiconductor (Wuxi) Ltd. in the People's Republic of China; Clarification of Scope of Entries in Supplement

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the existing Authorization Validated End-User (VEU) listings for four VEUs in the People's Republic of China (PRC). Specifically, BIS amends Supplement No. 7 to part 748 of the EAR to update VEU Advanced Micro Devices China Inc.'s (AMD China) current list of eligible destinations. BIS also amends the authorization of VEU Lam Research Corporation (Lam) by updating the addresses of ten eligible destinations and reformatting the list of Lam's existing eligible destinations into groups associated with specific eligible items. BIS also updates the EAR to amend the addresses and lists of eligible items for VEUs SK hynix Semiconductor (China) Ltd. and SK hynix Semiconductor (Wuxi) Ltd. Finally, BIS amends Supplement No. 7 to part 748 of the EAR to include language reminding exporters that the language in the Supplement does not supersede other requirements in the EAR.

These amendments to the authorizations of the named VEUs are not the result of activities of concern. The respective changes were prompted by factors arising from the companies' normal course of business or are being done at the request of the companies.

DATES: This rule is effective January 16, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Nies-Vogel, Chair, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue NW., Washington, DC 20230; by telephone: (202) 482–5991, fax: (202) 482–3991, or email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User

Validated end-users (VEUs) are designated entities located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license. The names of the VEUs, as well as the date they were so designated, and their respective eligible destinations and items are identified in Supplement No. 7 to part 748 of the EAR. Under the terms described in that supplement, VEUs may obtain eligible items without an export license from BIS. Eligible items may include commodities, software, and technology, except those controlled for missile technology or crime control reasons.

VEUs are reviewed and approved by the U.S. Government in accordance with the provisions of Section 748.15 and Supplement Nos. 8 and 9 to part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy and Commerce, and other agencies, as appropriate, is responsible for administering the VEU program. BIS amended the EAR in a final rule on June 19, 2007 (72 FR 33646) to create Authorization VEU.

Amendment to Existing Validated End-User Authorizations in the PRC

Revisions to the List of Eligible Destinations for Advanced Micro Devices China, Inc.

In this rule, BIS amends Supplement No. 7 to part 748 of the EAR to update two eligible destinations for Advanced Micro Devices China, Inc.'s (AMD China). Specifically, BIS updates the address of Advanced Micro Devices (Shanghai) Co., Ltd. by adding the country name to the address, and the address of AMD Technology Development (Beijing) Co., Ltd. by removing the floor designation in the address.

Names and Former Addresses of Facilities

AMD Technologies (China) Co., Ltd., No. 88, Su Tong Road, Suzhou, China 215021.

Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park 1387 Zhangdong Rd., Pudong, Shanghai, 201203.

AMD Technology Development (Beijing) Co., Ltd., 18F, North and South Buildings, RaycomInfotech Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.

Names and Current Addresses of Facilities

AMD Technologies (China) Co., Ltd., No. 88, Su Tong Road, Suzhou, China 215021.

Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park, 1387 Zhangdong Rd., Pudong, Shanghai, China 201203.

AMD Technology Development (Beijing) Co., Ltd., North and South Buildings, RaycomInfotech Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.

In addition, BIS adds a new eligible destination, AMD Products (China) Co. Ltd., to AMD's current list of eligible destinations in the PRC, as follows:

Additional Eligible Destination

AMD Products (China) Co. Ltd., North and South Buildings, RaycomInfotech Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.

Revisions to the List of Eligible Destinations and the List of Eligible Items (by ECCN) for Lam Research Corporation

In this rule, BIS amends Supplement No. 7 to part 748 to revise the eligible destinations and eligible items authorized for VEU Lam Research Corporation (Lam). Specifically, BIS updates the addresses of ten of Lam's existing eligible destinations and reformats Lam's existing eligible destinations into two groups, each with distinct lists of eligible items. The specific changes to Lam's authorization are as follows:

Names and Former Addresses of Facilities

Lam Research (Shanghai) Service Co., 1st Floor, Area C, Hua Hong Science & Technology Park, 177 Bi Bo Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203.

Lam Research Shanghai Co., Ltd., No. 1 Jilong Rd., Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131.

Lam Research International Sarl (Lam Shanghai Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 3869, Longdong Avenue, Pudong New District, Shanghai, China 201203.

Lam Research International Sarl (Lam Shanghai Warehouse; WGQ Bonded Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 3869, Longdong Avenue, Pudong New District, Shanghai, China 200131.

Lam Research Service Co., Ltd. (Beijing Branch), Rm 1010, Zhaolin Building, No. 15 Rong Hua Zhong Road, BDA, Beijing, China 100176.

Lam Research International Sarl (Lam Beijing Warehouse), Beijing Lam Electronics Tech Center, No. 8 Building, No.1, Disheng North Street, BDA, Beijing, China 100176.

Lam Research Service Co., Ltd., Wuxi Representative Office, Singapore International Park, 6 #302, No. 89 Xing Chuang, 4 Road, New District, Wuxi, Jiangsu, China 214028.

Lam Research International Sarl (Wuxi EPZ Bonded Warehouse), c/o HMG WHL Logistic (Wuxi) Co., Ltd., F1, Area 4, No. 1, Plot J3, No. 5 Gaolang East Road, Export Processing Zone, Wuxi, China 214028.

Lam Research Service Co., Ltd., Wuhan Representative Office, No. 1 Guanshan Road, Donghu Development Zone, Room E4–302, Optical Valley Software Park, Wuhan, Hubei, China 430074.

Lam Research Semiconductor (Suzhou) Co., Ltd. (Suzhou), A Division of Lam Research International Sarl, A–2 Building, Export Processing Zone, Suzhou New District, Jiangsu Province, China 215151.

Lam Research International Sarl (Lam Beijing Warehouse), Building 3, No. 9 Ke Chuang Er Street, Beijing Economic Technology Development Zone, Beijing, China 100176.

Lam Research International Sarl (Wuhan TSS), c/o HMG Wuhan Logistic Co., Ltd., 1st—2nd Floor, No. 5 Building, Hua Shi Yuan Er Road, Optical Valley Industry Park, East-lake Hi-Tech Development Zone, Wuhan City, Hubei Province, China 430223.

Names and Current Addresses of Facilities

Lam Research Service Co., Ltd., 1st Floor, Area C, Hua Hong Science & Technology Park, 177 Bi Bo Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203.

Lam Research (Shanghai) Co., Ltd., No. 1 Jilong Rd., Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131.

Lam Research Service Co., Ltd. (Beijing Branch), Rm 1010, Zhaolin Building, No. 15 Rong Hua Zhong Road, Beijing Economic & Technological Development Area, Beijing, China 100176.

Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing Lam Electronics Tech Center, No. 8 Building, No. 1, Disheng North Street, Beijing Economic & Technological Development Area, Beijing, China 100176.

Lam Research Service Co., Ltd., Wuxi Representative Office, Room 302, Building 6, Singapore International Park, No. 89 Xing Chuang Si Road, Wuxi New District, Wuxi, Jiangsu, China 214028.

Lam Research International Sarl (Wuxi EPZ Bonded Warehouse), c/o HMG WHL Logistic (Wuxi) Co., Ltd., 1st Fl, Area 4, No. 1, Plot J3, No. 5 Gaolang East Road, Export Processing Zone, Wuxi, China 214028.

Lam Research Service Co., Ltd., Wuhan Representative Office, Room 302, Guanggu Software Park Building E4, No. 1 Guanshan Road, Donghu Development Zone, Wuhan, Hubei Province, China 430074.

Lam Research International Sarl (Lam Beijing Warehouse), c/o HMG Hi-tech Logistics (Beijing) Co., Ltd., Building 3, No. 9 Ke Chuang Er Street, Beijing Economic Technological Development Area, Beijing, China 100176.

Lam Research International Sarl (Wuhan TSS), c/o HMG Wuhan Logistic Co., Ltd., 1st—2nd Floor, Area B, No. 5

Building, Hua Shi Yuan Er Road, Eastlake Hi-Tech Development Zone, Wuhan, Hubei Province, China 430223.

Lam Research International Sarl (Lam Shanghai Warehouse; WGQ Bonded Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 55, Fei la Road, Waigaoqiao Free Trade Zone, Pudong New Area, Shanghai, China 200131.

Lam Research International Sarl (Lam Shanghai Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 3869, Longdong Avenue, Pudong New District, Shanghai, China 201203.

Lam Research Semiconductor (Suzhou) Co., Ltd. (Suzhou), A Division of Lam Research International Sarl, A–2 Building, Export Processing Zone, Suzhou New District, Jiangsu Province, China 215151.

Eligible Items (by ECCN) and Their Eligible Destinations

The items identified by ECCN below may be exported to the following eligible destinations:

- Lam Research International Sarl (Lam Shanghai Warehouse);
- Lam Research International Sarl (Lam Shanghai Warehouse; WGQ Bonded Warehouse);
- Lam Research International Sarl (Lam Beijing Warehouse);
- Lam Research International Sarl (Wuxi EPZ Bonded Warehouse);
- Lam Research International Sarl (Lam Beijing Warehouse); and
- Lam Research International Sarl (Wuhan TSS).

The items identified here may be exported to the Lam facilities listed immediately above: ECCNs 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to specially designed components and accessories), 3D001 (limited to ''software'' (excluding source code) specially designed for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) specially designed for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' of equipment controlled by ECCN 3B001).

The items identified by ECCN below may be exported to the following eligible destinations:

- Lam Research Service Co., Ltd.;
- Lam Research (Shanghai) Co., Ltd.;
- Lam Research Service Co., Ltd. (Beijing Branch);
- Lam Research Service Co., Ltd. Wuxi Representative Office;
- Lam Research Service Co., Ltd. Wuhan Representative Office; and
- Lam Research Semiconductor (Suzhou) Co., Ltd. (Suzhou).

The items identified here may be exported to the Lam facilities listed immediately above: ECCNs 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to specially designed components and accessories), 3D001 (limited to ''software'' (excluding source code) specially designed for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) specially designed for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' or ''production'' (limited to those stages that support integration, assembly (mounting), inspection, testing, and quality assurance) of equipment controlled by ECCN 3B001).

Revisions to the List of Eligible Destinations for SK hynix Semiconductor (China) Ltd. and SK hynix Semiconductor (Wuxi) Ltd.

In this rule, BIS also amends the EAR to include the postcodes for the addresses of VEUs SK hynix Semiconductor (China) Ltd. and SK hynix Semiconductor (Wuxi) Ltd. (collectively, ''SK hynix China''). The updated addresses are as follows:

Name and Current Address of SK hynix Semiconductor (China) Ltd.

SK hynix Semiconductor (China) Ltd., Lot K7/K7–1, Export Processing Zone, Wuxi, Jiangsu, China 214028.

Name and Current Address of SK hynix Semiconductor (Wuxi) Ltd.

SK hynix Semiconductor (Wuxi) Ltd., Lot K7/K7–1, Export Processing Zone, Wuxi, Jiangsu, China 214028.

BIS also removes ECCN 3B001.d from the list of eligible items in Supplement No. 7 to part 748 for SK hynix Semiconductor (China) Ltd. and SK hynix Semiconductor (Wuxi) Ltd. to conform with changes to the Commerce Control List (Supplement No. 1 to part 774 of the EAR) in ''Wassenaar Arrangement 2011 Plenary Agreements Implementation: Commerce Control List, Definitions, New Participating State (Mexico) and Reports,'' published July 2, 2012 (77 FR 39354).

Former List of Eligible Items for SK hynix China

3B001.a, 3B001.b, 3B001.c, 3B001.d, 3B001.e, and 3B001.f.

Current List of Eligible Items for SK hynix China

3B001.a, 3B001.b, 3B001.c, 3B001.e, and 3B001.f.

The amendments to the VEU authorizations for AMD China, Lam, and SK hynix China, as approved by the ERC, were prompted by factors arising from the companies' normal course of business or were requested by the companies. None of the amendments were the result of activities of concern by the companies.

Revision to Supplement No. 7 to Part 748 of the EAR Table

Finally, this rule amends Supplement No. 7 to part 748 of the EAR to include language reminding exporters that the language in the Supplement does not supersede requirements elsewhere in the EAR. The new language reads as follows: ''Nothing in this Supplement shall be deemed to contradict other provisions in the EAR, including but not limited to § 748.15(c).'' This addition is intended to remind exporters that items controlled for missile technology and/or crime control reasons are not eligible for export, reexport or transfer (in-country) under Authorization VEU.

Since August 21, 2001, the Export Administration Act (the Act) has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), as extended most recently by the Notice of August 15, 2012, 77 FR 49699 (August 16, 2012), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. This rule involves collections previously approved by the Office of Management and Budget (OMB) under Control Number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 43.8 minutes to prepare and submit form BIS–748; and for recordkeeping, reporting and review requirements in connection with Authorization VEU, which carries an estimated burden of 30 minutes per submission. This rule is expected to result in a decrease in license applications submitted to BIS. Total burden hours associated with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and OMB Control Number 0694–0088 are not expected to increase significantly as a result of this rule.

Notwithstanding any other provisions of law, no person is required to respond nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), BIS finds good cause to waive requirements that this rule be subject to notice and the opportunity for public comment because such notice and comment here are unnecessary and contrary to the public interest. In determining whether to grant VEU designations, a committee of U.S. Government agencies evaluates information about and commitments made by candidate companies, the nature and terms of which are set forth in 15 CFR part 748, Supplement No. 8. The criteria for evaluation by the committee are set forth in 15 CFR 748.15(a)(2).

The information, commitments, and criteria for this extensive review were all established through the notice of proposed rulemaking and public comment process (71 FR 38313 (July 6, 2006) (proposed rule), and 72 FR 33646 (June 19, 2007) (final rule)). Given the similarities between the authorizations provided under the VEU program and export licenses (as discussed further below), the publication of this information does not establish new policy. In publishing this final rule, BIS simply amends four VEU authorizations by updating the eligible destinations of the four end-users and revising the eligible items of one of the four end-users. Additionally, BIS is adding language reminding exporters that the language in Supplement No. 7 to part 748 does not supersede requirements elsewhere in the EAR. These changes have been made within the established regulatory framework of the Authorization VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR.

Publication of this rule in other than final form is unnecessary because the authorizations granted in the rule are consistent with the authorizations granted to exporters for individual licenses (and amendments or revisions thereof), which do not undergo public review. In addition, as with license applications, VEU authorization applications contain confidential business information, which is necessary for the extensive review conducted by the U.S. Government in assessing such applications. Under the Export Administration Act, such information is withheld from public disclosure unless determined to be in the national interest. This information is extensively reviewed according to the criteria for VEU authorizations, as set out in 15 CFR 748.15(a)(2). Additionally, just as the interagency reviews license applications, the authorizations granted under the VEU program involve interagency deliberation and result from review of public and non-public sources, including licensing data, and the measurement of such information against the VEU authorization criteria. Given the nature of the review, and in light of the parallels between the VEU application review process and the review of license applications, public comment on this authorization and subsequent amendments prior to publication is unnecessary. Moreover, because, as noted above, the criteria and process for authorizing and administering VEUs were developed with public comments, allowing additional public comment on this amendment to individual VEU authorizations, which was determined according to those criteria, is unnecessary. Finally, allowing for prior public notice and comment is contrary to the public interest because it could cause confusion with the VEU status of the four companies identified in this rule due to the changes made to their addresses and items that may be exported, reexported or transferred (in-country) without a license to one of those companies. Regarding the addition of language to Supplement No. 7 to part 748 of the EAR, allowing for public comment and notice is unnecessary because the new language clarifies existing requirements; it does not create new requirements.

Section 553(d) of the APA generally provides that rules may not take effect earlier than thirty (30) days after they are published in the **Federal Register**. BIS finds good cause to waive the requirement of 5 U.S.C. 553(d)(3) to delay the effectiveness of this regulation, because such a delay is unnecessary. BIS is simply amending four VEU authorizations by updating the ''Eligible Destinations'' of the four end-users and revising the ''Eligible Items (by ECCN)'' of one of the four end-users, in addition to adding language reminding exporters that the language in the Supplement No. 7 to part 748 does not supersede requirements elsewhere in the EAR. These changes have been made within the established regulatory framework of the Authorization VEU program. Further, this rule does not abridge the rights of the public or eliminate the public's option to export under any of the forms of authorization set forth in the EAR. Delaying this action's effectiveness could cause confusion with the VEU status of the companies identified in this rule due to the changes made to their addresses and items that may be exported, reexported or transferred (in-country) without a license. Regarding the addition of language to Supplement No. 7 to part 748, delaying this action's effectiveness is unnecessary because the new language clarifies existing requirements; it does not create new requirements. Accordingly, it would be unnecessary and contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required under the APA or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable and no regulatory flexibility analysis has been prepared.

List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

■ 1. The authority citation for 15 CFR part 748 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012).

■ 2. Supplement No. 7 to Part 748 is amended:

■ a. By adding a sentence below the first row of column headings; and

■ b. By revising the entries for ''Advanced Micro Devices China, Inc.,'' ''Lam Research Corporation,'' ''SK hynix Semiconductor (China) Ltd.,'' and ''SK hynix Semiconductor (Wuxi) Ltd.'' in ''China (People's Republic of)'' as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU); LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS

Country	Validated end user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to § 748.15(c).				
China (People's Republic of).	Advanced Micro Devices China, Inc.	3D002, 3D003, 3E001 (limited to ''technology'' for items classified under 3C002 and 3C004 and ''technology'' for use during the International Technology Roadmap for Semiconductors (ITRS) process for items classified under ECCNs 3B001 and 3B002), 3E002 (limited to ''technology'' for use during the ITRS process for items classified under ECCNs 3B001 and 3B002), 3E003.e (limited to the ''development'' and ''production'' of integrated circuits for commercial applications), 4D001, 4D002 and 4E001 (limited to the ''development'' of products under ECCN 4A003).	AMD Technologies (China) Co., Ltd., No. 88, Su Tong Road, Suzhou, China 215021. Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 46, 47, 48 & 49, River Front Harbor, Zhangjiang Hi-Tech Park, 1387 Zhangdong Rd., Pudong, Shanghai, China 201203 AMD Technology Development (Beijing) Co., Ltd., North and South Buildings, RaycomInfotech, Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190. AMD Products (China) Co. Ltd., North and South Buildings, RaycomInfotech Park, Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.	75 FR 25763, 5/10/10. 76 FR 2802, 1/18/11. 78 FR [INSERT FR PAGE NUMBER] 1/16/13.
*	*	* *	*	* *
	Lam Research Corporation.	*These Items Authorized for those Lam's Destinations Identified by a single asterisk (*):* 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to specially designed components and accessories), 3D001 (limited to ''software'' (excluding source code) specially designed for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) specially designed for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' of equipment controlled by ECCN 3B001).	*Lam Research International Sarl (Lam Shanghai Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 3869, Longdong Avenue, Pudong New District, Shanghai, China 201203. *Lam Research International Sarl (Lam Shanghai Warehouse; WGQ Bonded Warehouse), c/o HMG Supply Chain (Shanghai) Co., Ltd., No. 55, Fei la Road, Waigaoqiao Free Trade Zone, Pudong New Area, Shanghai, China 200131. *Lam Research International Sarl (Lam Beijing Warehouse), c/o Beijing Lam Electronics Tech Center, No. 8 Building No. 1, Disheng North Street, Beijing Economic & Technological Development Area, Beijing, China 100176. *Lam Research International Sarl (Wuxi EPZ Bonded Warehouse), c/o HMG WHL Logistic (Wuxi) Co., Ltd., 1st Fl, Area 4, No. 1, Plot J3, No. 5 Gaolang East Road, Export Processing Zone, Wuxi, China 214028.	75 FR 62462, 10/12/10. 77 FR 10955, 2/24/12. 78 FR [INSERT FR PAGE NUMBER] 1/16/13.

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU); LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS—Continued

Country	Validated end user	Eligible items (by ECCN)	Eligible destination	**Federal Register** citation
			* Lam Research International Sarl (Lam Beijing Warehouse), c/o HMG Hi-tech Logistics (Beijing) Co., Ltd., Building 3, No. 9 Ke Chuang Er Street, Beijing Economic Technological Development Area, Beijing, China 100176. * Lam Research International Sarl (Wuhan TSS), c/o HMG Wuhan Logistic Co., Ltd., 1st–2nd Floor, Area B, No. 5 Building, Hua Shi Yuan Er Road, East-lake Hi-Tech Development Zone, Wuhan, Hubei Province, China 430223.	
		These Items Authorized for those Lam's Destinations Identified by two asterisks (**): 2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 2B350.i, 3B001.c and 3B001.e (items classified under ECCNs 3B001.c and 3B001.e are limited to specially designed components and accessories), 3D001 (limited to ''software'' (excluding source code) specially designed for the ''development'' or ''production'' of equipment controlled by ECCN 3B001), 3D002 (limited to ''software'' (excluding source code) specially designed for the ''use'' of equipment controlled by ECCN 3B001), and 3E001 (limited to ''technology'' according to the General Technology Note for the ''development'' or ''production'' (limited to those stages that support integration, assembly (mounting), inspection, testing, and quality assurance) of equipment controlled by ECCN 3B001).	** Lam Research Service Co., Ltd., 1st Floor, Area C, Hua Hong Science & Technology Park, 177 Bi Bo Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203.. ** Lam Research (Shanghai) Co., Ltd., No. 1 Jilong Rd., Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131. ** Lam Research Service Co., Ltd. (Beijing Branch), Rm 1010, Zhaolin Building, No. 15 Rong Hua Zhong Road, Beijing Economic & Technological Development Area, Beijing, China 100176. ** Lam Research Service Co., Ltd., Wuxi Representative Office, Room 302, Building 6, Singapore International Park, No. 89 Xing Chuang Si Road, Wuxi New District, Wuxi, Jiangsu, China 214028. ** Lam Research Service Co., Ltd., Wuhan Representative Office, Room 302, Guanggu Software Park Building E4, No. 1 Guanshan Road, Donghu Development Zone, Wuhan, Hubei Province, China 430074. ** Lam Research Semiconductor (Suzhou) Co., Ltd. (Suzhou), A Division of Lam Research International Sarl, A–2 Building, Export Processing Zone, Suzhou New District, Jiangsu Province, China 215151.	
*	*	* *	*	* *
	SK hynix Semiconductor (China) Ltd.	3B001.a, 3B001.b, 3B001.c, 3B001.e, and 3B001.f.	SK hynix Semiconductor (China) Ltd., Lot K7/K7–1, Export Processing Zone, Wuxi, Jiangsu, China 214028.	75 FR 62462, 10/12/10. 77 FR 40258, 7/9/12. 78 FR [INSERT FR PAGE NUMBER] 1/16/13.
	SK hynix Semiconductor (Wuxi) Ltd.	3B001.a, 3B001.b, 3B001.c, 3B001.e, and 3B001.f.	SK hynix Semiconductor (Wuxi) Ltd., Lot K7/K7–1, Export Processing Zone, Wuxi, Jiangsu, China 214028.	75 FR 62462, 10/12/10. 77 FR 40258, 7/9/12. 78 FR [INSERT FR PAGE NUMBER] 1/16/13.
*	*	* *	*	* *

Dated: January 10, 2013.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2013–00770 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9608]

RIN 1545–BI85

Disclosure or Use of Information by Preparers of Returns; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations and removal of temporary regulations.

SUMMARY: This document corrects the final regulations and removal of temporary regulations (TD 9608) that were published in the **Federal Register** on Friday, December 28, 2012 (77 FR 76400) relating to the disclosure or use of tax return information by tax return preparers.

DATES: These corrections are effective on January 16, 2013, and are applicable on December 28, 2012.

FOR FURTHER INFORMATION CONTACT: Emily Lesniak, (202) 622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations and removal of temporary regulations (TD 9608) that are the subject of this correction are under section 7216 of the Internal Revenue Code.

Need for Correction

As published, TD 9608 contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the correction to final regulations and removal of temporary regulations (TD 9608), which was the subject of FR. Doc. 2012–31185, is corrected as follows:

1. On page 76403, column 2, in the preamble, under the paragraph heading ''*4. Effective Date of TD 9478'',* third line, the language ''2(o) of the temporary regulations'', is corrected to read, ''2T(o) of the temporary regulations''.

2. On page 76403, column 2, in the preamble, under the paragraph heading ''*4. Effective Date of TD 9478,* last line of the column, the language ''§ 301.7216–2(o) was made effective only'', is corrected to read ''§ 301.7216–2T(o) was made effective only''.

3. On page 76403, column 3, in the preamble, under the paragraph heading ''*4. Effective Date of TD 9478,* line 4 from the top of the column, the language ''provided for Notice 2009–13 nor those'', is corrected to read, ''provided for in Notice 2009–13 nor those''.

4. On page 76403, column 3, in the preamble, under the paragraph heading ''*4. Effective Date of TD 9478,* line 10 from the top of the column, the language ''if § 301.7216–2(o) had not been, is corrected to read, ''if § 301.7216–2T(o) had not been''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2013–00749 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9607]

RIN 1545–BJ37

Partners Distributive Share; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document corrects final regulations (TD 9607) that was published in the **Federal Register** on Friday, December 28, 2012 (77 FR 76380) regarding the application of the substantiality de minimis rule. In the interest of sound tax administration, this rule is being made inapplicable. These final regulations affect partnerships and their partners.

DATES: This correction is effective on January 16, 2013 and is applicable on December 28, 2012.

FOR FURTHER INFORMATION CONTACT: Rebecca Kahane (202) 622–3050 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of final regulations (TD 9607) that is the subject of this correction is under section 704 of the Internal Revenue Code.

Need for Correction

As published, TD 9607 contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the correction to final regulations (TD 9607), which was the subject of FR. Doc. 2012–31155, is corrected as follows:

1. On page 76380, column 1, in the preamble, under the caption **FOR FURTHER INFORMATION CONTACT**, first line, the language ''Rebecca Kahanel, at (202) 622–3050 (not'', is corrected to read ''Rebecca Kahane, at (202) 622–3050 (not''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedure and Administration.

[FR Doc. 2013–00748 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 18

Appointing Authority for Military Commissions

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule removes 32 CFR part 18 concerning the Appointing Authority for Military Commissions. This rule pertains to a military function of the United States and is exempt from rulemaking requirements. Previously, this rule was published for informational purposes only. As a result of the enactment of Military Commissions Act of 2009, the Deputy Secretary's issuance of the Regulation for Trial by Military Commissions on November 6, 2011, and his cancellation of DoD Directive 5105.70, ''Appointing Authority for Military Commissions,'' this regulation is no longer required.

DATES: *Effective Date:* This rule is effective January 16, 2013.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: For additional information on Military Commissions, see Military Commissions Act of 2009.

List of Subjects in 32 CFR Part 18

Military law.

PART 18—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 18 is removed.

Dated: January 10, 2013.

Morgan F. Park,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–00813 Filed 1–15–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–1092]

RIN 1625–AA00

Safety Zone Within the Lower Portion of Anchorage #9, Mantua Creek Anchorage; Paulsboro, NJ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will be establishing a temporary safety zone around the southern one-third of Anchorage #9 (Mantua Creek Anchorage) due to dredging operations. The Dredge Florida will be working along with several support barges and tugs to install approximately 8,000 feet of submerged pipeline and approximately 3,000 feet of floating pipeline crossing through this portion of the anchorage. This regulation is necessary to provide for the safety of life on the navigable waters of the Mantua Creek Anchorage. This closure is intended to restrict vessel anchoring to protect mariners from the hazards associated with an ongoing dredging operation.

DATES: This rule is effective with actual notice from December 20, 2012 until January 16, 2013. This rule is effective in the **Federal Register** from January 16, 2013 until January 31, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–1092]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email If you have questions on this temporary rule, call or email Lieutenant Veronica Smith, U.S. Coast Guard, Sector Delaware Bay, Acting Chief of Waterways Management Division, Coast Guard; telephone 215–271–4851, email *veronica.l.smith@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because final details for this dredging operation were not provided until it was too late to solicit public comment. As such, it is impracticable to provide a fill comment period due to lack of time. The dredging will begin on December 20th, 2012 and will continue until January 31, 2013 unless completed earlier.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** for the reasons cited above. Delaying this regulation's effective date would be impracticable because immediate action is needed to provide for the safety of life and property from the hazards associated with the dredging operation.

B. Basis and Purpose

The Great Lakes Dredging Company has been working with the Army Corps of Engineers on the Delaware River channel widening project. A portion of this project requires the use of submerged and floating pipelines crossing the lower portion of the Mantua Creek Anchorage. Due to the presence of the submerged pipeline, it is dangerous for vessels to anchor in the southern one-third of the anchorage. A safety zone is necessary because there will be an ongoing dredging operation to deepen the Delaware River channel in the Mifflin and Billingsport Ranges from December 20, 2012 until January 31, 2013. The Captain of the Port believes a safety zone is needed to ensure the safety of life and property of all mariners and vessels transiting the local area.

C. Discussion of the Final Rule

The Coast Guard Captain of the Port Delaware Bay is temporarily establishing a safety zone closing the southern one-third of the Mantua Creek Anchorage from on December 20, 2012 until January 31, 2013. This rule will be enforced until all dredging operations are competed, unless enforcement of the zones is cancelled earlier by the Captain of the Port. The Captain of the Port will reopen this portion of the anchorage once all submerged pipeline has been recovered and dredging operations are completed. At such time, notice that the temporary closure of the anchorage is no longer in effect will be broadcast to mariners.

The boundary line for the temporary safety zone includes the southern one-third portion of Mantua Creek Anchorage, beginning at position 39° 51.573 N–075° 13.557 W and extending to the southern boundary according to NOAA chart 12312. Vessels will not be permitted to anchor in this portion of Mantua Creek Anchorage unless they receive authorization from the Captain of the Port Delaware Bay or her representative. Such requests must be made 24 hours prior to the intended use of the Mantua Creek Anchorage. Vessels may contact the Captain of the Port Delaware Bay or her representative in order to obtain authorization by contacting Coast Guard Sector Delaware Bay at: (215) 271–4940. After evaluating the current conditions and status of dredging operation, the Captain of the Port Delaware Bay or her representative will notify the requesting vessel whether they are authorized to anchor in the safety zone within Mantua Creek Anchorage, and will provide any other directions for their request.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based numerous statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving

Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. Although this regulation will restrict access to the regulated area, the effect of this rule will not be significant because: (i) The Coast Guard will make extensive notification of the closure to the maritime public via maritime advisories so mariners can alter their plans accordingly; (ii) vessels may still be permitted to anchor in the safety zone with the permission of the Captain of the Port on a case-by-case basis; and (iii) this rule will be enforced for only the duration of dredging operations.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of the vessels intending to anchor in the safety zone within Mantua Creek Anchorage from December 20, 2012 until January 31, 2012 or until all dredging operations are completed, unless cancelled earlier by the Captain of the Port.

This closure will not have a significant economic impact on a substantial number of small entities for the following reason: Vessels will be allowed utilize the upper two-thirds of the Mantua Creek Anchorage, and nearby anchorages with permission of the Coast Guard Captain of the Port Delaware Bay or her representative. Sector Delaware Bay will issue maritime advisories widely accessible to users of the Anchorage informing them of the safety zone.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves implementation of regulations within 33 CFR Part 165, applicable to safety zones on the navigable waterways. This zone will temporarily restrict vessels from utilizing the southern one-third of Mantua Creek Anchorage in order to protect the safety of life and property on the waters while dredging operations are conducted. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An

environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–1092, to read as follows:

§ 165.T05–1092 Safety Zone Within the Lower Portion of Anchorage #9, Mantua Creek Anchorage; Paulsboro, NJ.

Location: The southern one-third of the Anchorage #9 (Mantua Creek Anchorage), below position 39° 51.573 N—075° 13.557 W.

(a) *Enforcement period:* This rule will be enforced from December 20, 2012 until January 31, 2013, unless cancelled earlier by the Captain of the Port.

(b) *Regulations:* All persons are required to comply with the general regulations governing safety zones in 33 CFR 165.23 of this part.

(1) All persons and vessels utilizing the southern one-third portion of the anchorage must be authorized by the Captain of the Port or her representative.

(2) All persons or vessels wishing to anchor within the safety zone must request authorization to do so from the Captain of the Port or her representative 24 hours prior to the intended time of transit.

(3) Vessels granted permission to anchor must do so in accordance with the directions provided by the Captain of the Port or her representative to the vessel.

(4) To seek permission to anchor in the safety zone, the Captain of the Port or her representative can be contacted via Sector Delaware Bay Command Center (215) 271–4940.

(5) This section applies to all vessels wishing to anchor in the safety zone within Mantua Creek Anchorage except vessels that are engaged in the following operations:

(i) Enforcing laws;

(ii) Servicing aids to navigation, and

(iii) Emergency response vessels.

(6) No person may enter a safety zone unless authorized by the COTP or the District Commander;

(7) No person may bring or cause to be brought into a safety zone any vehicle, vessel, or object unless authorized by the COTP or the District Commander;

(8) No person may remain in a safety zone or allow any vehicle, vessel, or object to remain in a safety zone unless authorized by the COTP or the District Commander; and

(9) Each person in a safety zone who has notice of a lawful order or direction shall obey the order or direction of the COTP or District Commander issued to carry out the purposes of this subpart.

(c) *Definitions.*

(1) *The Captain of the Port* means the Commanding Officer of Sector Delaware Bay or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on her behalf.

(2) [Reserved]

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the Safety Zone by Federal, State, and local agencies.

Dated: December 20, 2012.

T.C. Wiemers,

Captain, U.S. Coast Guard, Alternate Captain of the Port Delaware Bay.

[FR Doc. 2013–00845 Filed 1–15–13; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0962; FRL–9371–1]

Fluroxypyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluroxypyr in or on rice bran and rice grain. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2013. Objections and requests for hearings must be received on or before March 18, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0962, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8072; email address: *benbow.bethany@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection

or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0962 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 18, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b). In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0962, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerances

In the **Federal Register** of December 30, 2011 (76 FR 82238) (FRL–9331–1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7928) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.535 be amended by establishing tolerances for residues of the herbicide, fluroxypyr 1–MHE and its acid metabolite, fluroxypyr, in or on rice at 1.5 parts per million (ppm) and rice bran at 3.0 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluroxypyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluroxypyr follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The active ingredient used in formulating end-use herbicide products is fluroxypyr 1-methylheptyl ester. However, since the ester form has been shown to rapidly hydrolyze to the acid form, the residues of fluroxypyr 1-methylheptyl ester along with its fluroxypyr acid metabolite (free and conjugated), are collectively expressed as ''fluroxypyr'' and are therefore regulated together for tolerance enforcement. In terms of toxicity, the ester and acid forms are considered the same.

Fluroxypyr has low acute toxicity by the oral and dermal routes of exposure and moderate to mild acute toxicity by the inhalation route of exposure, based on lethality studies. Fluroxypyr is not a dermal sensitizer, nor is it irritating to the skin; however, it is a mild eye irritant.

The kidney is the target organ for fluroxypyr following oral exposure to rats, mice, and dogs. In the rat, increased kidney weight, nephrotoxicity, and death were observed in both sexes in the 90-day feeding study, and increased kidney weight and microscopic kidney lesions were observed in both sexes in the chronic study. Increased kidney weight was also observed in maternal rats in the developmental toxicity study, and kidney effects (deaths due to renal failure; increased kidney weight, and microscopic kidney lesions) were observed in both sexes in the 2-generation reproduction study in rats. Although microscopic kidney lesions were observed in dogs in the 28-day feeding study, no kidney effects or other treatment related toxicity were seen in the chronic feeding study in dogs at the same doses used in the 28-day study. Microscopic kidney lesions were observed in mice following long-term exposure.

There was no evidence of increased susceptibility (quantitative/qualitative) following *in utero* exposure in rats and rabbits, or following pre and/or postnatal exposure in rats. Neither developmental toxicity nor reproductive toxicity was observed in rats. In rabbits, developmental toxicity was not observed following exposure to dose levels that resulted in maternal death; however, abortions were observed in rabbits following exposure to fluroxypyr at the limit dose. There was no evidence of neurotoxicity or neuropathology in any of the studies. An immunotoxicity study in rats found no indication of immunotoxicity. Fluroxypyr is classified ''not likely to be carcinogenic to humans'' due to lack of evidence to suggest carcinogenicity in the database, and there is no concern for its mutagenicity potential.

Specific information on the studies received and the nature of the adverse effects caused by fluroxypyr as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Fluroxypyr. Human Health Risk Assessment to Support Proposed New

Use on Rice,'' p. 15 in docket ID number EPA–HQ–OPP–2011–0962.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for fluroxypyr used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUROXYPYR FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	No adverse effects were identified following a single oral dose and there are no developmental concerns noted in the database.		
Chronic dietary (All populations)	NOAEL = 100 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×	Chronic RfD = 1 mg/kg/day. cPAD = 1 mg/kg/day	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Incidental oral (Short- and Intermediate term).	NOAEL = 100 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Inhalation (all durations)	Inhalation (or oral) study NOAEL = 100 mg/kg/day (inhalation and oral toxicity assumed to be equivalent). UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	Chronic/Carcinogenicity-Rat LOAEL = 500 mg/kg/day, based on kidney effects (increased kidney weights, alterations in clinical chemistry parameters indicative of impaired renal functions, and increase in severity of chronic progressive glomerulonephropathy in both sexes).
Cancer (Oral)	Classified as a ''Not Likely'' human carcinogen.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluroxypyr, EPA considered exposure under the petitioned-for tolerances as well as all existing fluroxypyr tolerances in 40 CFR 180.535. EPA assessed dietary exposures from fluroxypyr in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for fluroxypyr; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, ''What We Eat in America'' (NHANES/WWEIA) dietary survey conducted in 2003–2008. As to residue levels in food, EPA assumed tolerance-level residues with 100 percent crop treated (PCT) for all existing and proposed crop uses and default processing factors for processed commodities.

iii. *Cancer.* EPA has concluded that fluroxypyr does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluroxypyr. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluroxypyr in drinking water. These simulation models take into account data on the physical, chemical, and fate/ transport characteristics of fluroxypyr. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at

http://www.epa.gov/oppefed1/models/water/index.htm.

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of fluroxypyr for acute and chronic exposures are both estimated to be 540 parts per billion (ppb) for surface water and 0.055 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 540 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluroxypyr is currently registered for the following uses that could result in residential exposures: Residential turfgrass, golf courses, parks and sports fields. EPA assessed residential exposure using the following assumptions: Residential handler exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Since there are no toxicity findings for the short-term dermal route of exposure up to the limit dose, only inhalation exposure was assessed for residential handlers of fluroxypyr. The following exposure scenarios were assessed for residential handlers: Loading and applying liquids with manually pressurized hand-wands, hose-end sprayers, and backpack applicators.

For residential post-application exposure and risk estimates, EPA assumed that young children 1 to <2 years old may receive incidental oral post-application exposure to fluroxypyr from treated turf.

A residential bystander post-application inhalation exposure assessment was not performed for fluroxypyr at this time because the chemical has low vapor pressure, is applied at a low rate, and is not applied via airblast. Although a quantitative residential post-application inhalation exposure assessment was not performed as a result of pesticide drift from neighboring treated agricultural fields, an inhalation exposure assessment was performed for flaggers. This exposure scenario, for which no risks of concern were identified, is representative of a worse case inhalation (drift) exposure and may be considered protective of most outdoor agricultural and commercial post-application inhalation exposure scenarios. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not found fluroxypyr to share a common mechanism of toxicity with any other substances, and fluroxypyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluroxypyr does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased qualitative or quantitative susceptibility following *in utero* exposure in rats and rabbits or following pre and/or postnatal exposure in rats.

Fluroxypyr is neither a developmental nor a reproductive toxicant in rats. Fluroxypyr has been evaluated for potential developmental effects in the rat and rabbit (gavage administration). Maternal toxicity included death in rats and rabbits. There were no developmental effects in the rat, and while abortions were observed in the rabbit, they occurred only at the limit dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluroxypyr is complete.

ii. There is no indication that fluroxypyr is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluroxypyr results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes tolerance level residue estimates and assumes 100 PCT for all commodities. This assessment will not underestimate exposure/risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluroxypyr in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluroxypyr.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluroxypyr is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluroxypyr

from food and water will utilize 3.5% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluroxypyr is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluroxypyr.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,500 for adult handlers using a backpack sprayer, and 2,400 for children's postapplication oral exposure. Because EPA's level of concern for fluroxypyr is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, fluroxypyr is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluroxypyr.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluroxypyr is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluroxypyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/electron capture detection (GC/ECD methods GRM 96.02 and 96.03)) are available to enforce the tolerance expression. Fluroxypyr was previously tested through FDA's Multiresidue Methodology, Protocols C, D, and E and was found to be recovered. The results have been published in the FDA Pesticide Analytical Manual, Volume I. The GRM 96.02 and 96.03 methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Maximum Residue Limits (MRLs) established by Codex, Canada, or Mexico for any of the proposed commodities for fluroxypyr.

V. Conclusion

Therefore, tolerances are established for the combined residues of fluroxypyr 1–MHE and its acid metabolite fluroxypyr, in or on rice at 1.5 ppm and rice bran at 3.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 7, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.535, in paragraph (a), revise the introductory text and add alphabetically the following commodities to the table to read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the following raw agricultural commodities. Compliance with the established tolerance levels is determined by measuring only the sum of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3, 5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] calculated as the stoichiometric equivalent of fluroxypyr.

Commodity	Parts per million
* * * * *	
Rice, bran	3.0
Rice, grain	1.5
* * * * *	

* * * * *

[FR Doc. 2013–00562 Filed 1–15–13; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0038; FRL–9374–3]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiromesifen in or on tea, dried. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2013. Objections and requests for hearings must be received on or before March 18, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0038, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Jennifer Gaines, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5967; email address: *Gaines.Jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0038 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before March 18, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0038, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/

DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 4, 2012 (77 FR 20334–20337) (FRL–9340–4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7924) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, N.C. 27709. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for residues of spiromesifen, (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), in or on tea, dried at 50 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has changed the tolerance for tea, dried from 50 ppm to 40 ppm. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spiromesifen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spiromesifen follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Spiromesifen was classified as having low acute toxicity via the oral, dermal and inhalation routes of exposure. It was neither an eye nor dermal irritant, but showed moderate potential as a skin contact sensitizer. In short- and long-term animal toxicity tests, the critical effects observed were loss of body weight, adrenal effects (discoloration, decrease in fine vesticulation, and the presence of cytoplasmic eosinophilia in zona fasciculata cells), thyroid effects (increased thyroid stimulating hormone, increased thyroxine binding capacity, decreased T3 and T4 levels, colloidal alteration and thyroid follicular cell hypertrophy), liver effects (increased alkaline phosphatase, alanine transaminase (ALT) and decreased cholesterol, and triglycerides), and spleen effects (atrophy, decreased spleen cell count, and increased macrophages). There were no developmental or reproductive effects of concern following oral administration of spiromesifen in rats or rabbits. EPA concluded that spiromesifen is not likely to be carcinogenic to humans based on a lack of evidence of cancer in bioassays in rats and mice. There were no *in vivo* or *in vitro* mutagenic effects in mutagenicity testing with spiromesifen. Spiromesifen is not considered a neurotoxic chemical based on the chemical's mode of action and the available data from multiple studies, including acute and subchronic neurotoxicity studies.

Specific information on the studies received and the nature of the adverse effects caused by spiromesifen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Spiromesifen: Human-Health Risk Assessment for Request for Tolerance without U.S. Registration in/on Tea.'' at pages 20 to 24 in docket ID number EPA–HQ–OPP–2012–0038.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for spiromesifen used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPIROMESIFEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	Not applicable	None	An endpoint of concern attributable to a single dose was not identified. An aRfD was not established.
Chronic dietary (All populations)	NOAEL= 2.2 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.022 mg/kg/day.. cPAD = 0.022 mg/kg/day	2-generation reproduction study in rats. The parental systemic LOAEL = 8.81 mg/kg/day based on significantly decreased spleen weight (absolute and relative in parental females and F_1 males) and significantly decreased growing ovarian follicles in females.
Dermal short-term (1 to 30 days) and Intermediate-term (1 to 6 months).	None	None	No dermal, systemic, or developmental concerns.
Inhalation short-term (1 to 30 days) and Intermediate-Term (1 to 6 months).	Inhalation (or oral) study NOAEL = 21.1 mg/kg/day (inhalation absorption rate = 100%). HEC = 0.06 mg/L HED = 1.42 mg/kg/bw/day	LOC for MOE = 30 (3X interspecies and 10X intraspecies extrapolations).	Subchronic (30-day) inhalation toxicity study in rats & 5-day inhalation toxicity study in rats. LOAEL (5-day) = 134.2 mg/kg/day based on the clinical signs (tremors, clonic-tonic convulsions, reduced activity, bradypnea, labored breathing, vocalization, avoidance reaction, giddiness, piloerection, limp, emaciation, cyanosis, squatted posture, apathy, salivation, gross pathology (dark red areas or foci in the lungs, bloated stomachs, and pale liver), and decreased spleen weights.
Cancer (Oral, dermal, inhalation).	Spiromesifen has been classified as "not likely to be carcinogenic to humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). HEC = human human-equivalent concentration. HED = human human-equivalent dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spiromesifen, EPA considered exposure under the petitioned-for tolerances as well as all existing spiromesifen tolerances in 40 CFR 180.607. EPA assessed dietary exposures from spiromesifen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for spiromesifen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Cumulative Survey of Food Intake by Individuals, CSFII. As to residue levels in food, EPA assumed tolerance-level residues for all commodities except for the leafy-green and leafy-*Brassica* vegetable subgroups (4A, 4B, and 5B), spearmint and peppermint tops and oil, and tea. For these commodities, residues were also based on tolerance levels; however, a correction factor was applied to the tolerance levels to account for BSN 2060-4-hydroxymethyl metabolites of spiromesifen included in the risk assessment for these commodities. The additional metabolites, BSN 2060-4-hydroxymethyl and BSN 2060-4-hydroxymethyl-glucoside, were observed in the metabolism studies of lettuce only, comprising 21% of the total radioactive residues. Since the toxicity of the BSN 2060-4-hydroxymethyl metabolites is expected to be comparable to the parent compound, it was included in the risk assessment for leafy crops (including tea, subgroups 4A, 4B, and 5B and spearmint and peppermint tops and oil). To account for this additional exposure, the recommended tolerance level was multiplied by a correction factor of 1.3X, where 1.3 = (Metabolites in Risk Assessment)/(Metabolites in Tolerance Expression; concentrations from the lettuce metabolism study). Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors and 100 percent crop treated were assumed.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that spiromesifen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for spiromesifen. As discussed in Unit III.C.1.ii., for the leafy-greens and leafy *Brassica* greens subgroups (4A, 4B, and 5B) and spearmint and peppermint tops and oil, and tea, the residue values were adjusted upward to account for the metabolite BSN 2060-4-hydroxymethyl (free and conjugated).

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spiromesifen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spiromesifen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Provisional Cranberry Model and Screening Concentration in Ground Water (SCI–GROW) models the estimated drinking water concentrations (EDWCs) of spiromesifen for chronic exposures for non-cancer assessments are estimated to be 188 ppb for surface water and 86 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered

into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 188 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Spiromesifen is currently registered for the following uses that could result in residential exposures: Indoor and outdoor uses for the control of mites and whiteflies on ornamental plants in and around areas such as parks, golf courses, recreational areas, and residential and commercial buildings. EPA assessed residential exposure using the following assumptions: Residential handler inhalation exposure was assessed for adults mixing/loading/applying spiromesifen using handheld equipment to ornamentals. Details for the residential risk exposure and risk assessment are contained in the EPA public docket EPA–HQ–OPP–2012–0038 at *http://www.regulations.gov* in document ''Spiromesifen: Human-Health Risk Assessment for Request for Tolerance Without U.S. Registration in/on Tea'' on pp.15–19.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found spiromesifen to share a common mechanism of toxicity with any other substances, and spiromesifen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spiromesifen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rats or rabbits following *in utero* and/or postnatal exposure to spiromesifen. In the prenatal developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, developmental toxicity to the offspring occurred at equivalent or higher doses than parental toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spiromesifen is complete.

ii. There is no indication that spiromesifen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spiromesifen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spiromesifen in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spiromesifen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, spiromesifen is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spiromesifen from food and water will utilize 78% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spiromesifen is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, spiromesifen is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, spiromesifen is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spiromesifen is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children

from aggregate exposure to spiromesifen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography/tandem mass spectroscopy (HPLC/MS/MS)/Method BS001–P09–01 is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for spiromesifen in/on dried tea.

C. Response to Comments

There were no comments received.

D. Revisions to Petitioned-For Tolerances

Based on the analysis of the data supporting the petition, EPA has revised the proposed tolerance for tea, dried from 50 ppm to 40 ppm. EPA revised this tolerance level based on the highest-average field trial residue level and a processing factor for black tea.

V. Conclusion

Therefore, tolerances are established for residues of spiromesifen, (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), in or on tea, dried at 40 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 4, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.607, the table in paragraph (a)(1) is amended by adding, alphabetically, the commodity ''Tea, dry'' to read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * * * *	
Tea, dry	40
* * * * *	

* * * * *

[FR Doc. 2013–00728 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 1103210208–2676–02]

RIN 0648–BA89

High Seas Driftnet Fishing Moratorium Protection Act; Identification and Certification Procedures To Address Shark Conservation

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final action sets forth identification and certification procedures to implement provisions of the Shark Conservation Act, which amended the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act), to address shark conservation in areas beyond any national jurisdiction. This action also amends the definition of illegal, unreported, or unregulated (IUU) fishing for purposes of the Moratorium Protection Act.

DATES: This rule is effective January 16, 2013.

FOR FURTHER INFORMATION CONTACT: Laura Cimo, Trade and Marine Stewardship Division, Office of International Affairs, NMFS, at (301) 427–8359. More information on the Moratorium Protection Act can be found on the NMFS Web site at *http://www.nmfs.noaa.gov/msa2007/intlprovisions.html.*

SUPPLEMENTARY INFORMATION:

Background

On January 12, 2011, the National Marine Fisheries Service (NMFS) published a rule (76 FR 2011) establishing identification and certification procedures to address illegal, unreported, or unregulated (IUU) fishing activities and bycatch of protected living marine resources (PLMRs) pursuant to the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act) (50 CFR 300.200 *et seq.*) (16 U.S.C. 1826h–k). This action modifies those identification and certification procedures to reflect amendments to the Moratorium Protection Act made by the Shark Conservation Act (Pub. L. 111–348), enacted on January 4, 2011.

On July 10, 2012, NOAA published a proposed rule establishing identification and certification procedures to implement the international provisions of the Shark Conservation Act. This rule also proposed changes to the definition of IUU fishing for purposes of the Moratorium Protection Act (see 50 CFR 300.201). The background information on this action was published in the proposed rule (77 FR 40553, July 10, 2012) and is not repeated here.

Briefly, under these regulations, in addition to identifying nations based on IUU fishing or bycatch of protected living marine resources, NMFS will identify a foreign nation in a biennial report to Congress if fishing vessels of that nation have been engaged during the preceding calendar year in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks and the nation has not adopted a regulatory program for the conservation of sharks. Such conservation measures must be comparable to those of the United States, taking into account different conditions.

A brief summary of how NMFS intends to apply Section 609 of the Moratorium Protection Act and its implementing regulations is repeated below.

Application of IUU Fishing Identification Criteria

In addition to the regulatory changes identified above, NMFS has reconsidered the manner in which it applies Section 609 of the Moratorium Protection Act and its implementing regulations. To date, NMFS has primarily applied this Act and implementing regulations to identify a nation when the nation's vessels were engaged in IUU fishing activity that was directly attributable to specific vessel conduct.

After two cycles of identification, NMFS has determined that these provisions could be applied more broadly. In order to more comprehensively address IUU fishing, we must consider not only the prohibited actions of fishing vessels but also non-compliance in the form of action or inaction at the national level that leads to IUU fishing. To further this goal, NMFS will identify a nation based on the nation's actions or inactions that lead to fishing by vessels registered under their flag that is not in accordance with regional fishery management organization (RFMO) conservation and management measures.

For example, under the approach adopted in this final rule, NMFS could identify a nation when the nation has failed to implement measures that are required by a RFMO to which the United States is a party, and as a result the fishing vessels of that nation operated in a manner inconsistent with the relevant RFMO conservation and management measures.

This approach is consistent with the plain language of the statutory guidelines provided in section 609(e)(3)(A) of the Moratorium Protection Act for the IUU fishing definition. These statutory guidelines specifically mention certain RFMO conservation and management measures, such as catch limits or quotas, that must be implemented by nations that are parties to the RFMO and cannot necessarily be attributed to specific fishing vessels. For example, RFMOs can establish quotas for their member nations. Each nation bears the responsibility for implementing and adhering to the quota it received. Individual fishing vessels, therefore, cannot be found in violation of the RFMO's quota, but action or inaction by the flag nation could result in fishing activity in violation of the quota. In addition to specific situations mentioned in the minimum statutory guidelines for the IUU fishing definition, there are other circumstances in which fishing activities might violate RFMO measures because of a nation's failure to govern its own fishing vessels or carry out its own responsibilities. For example, RFMOs require parties to implement data reporting requirements. In most cases, the nations, and not individual vessels, compile and report the requisite information to comply with RFMO conservation and management measures. Because many measures are inherently a nation's responsibility, Congress evidently intended NMFS to be able to identify a nation based on its failure to fulfill the requirements of the relevant RFMO and the operations of the nation's fisheries in light of this failure.

Under the approach adopted in this final rule, a nation could be identified for fishing activities that were illegal, unregulated, or unreported because of national action or inaction, including, consistent with the examples discussed above, fishing activities that resulted in the nation exceeding a harvest quota granted by the relevant RFMO because the nation failed to implement measures to prevent such overharvest, and fishing activities that were not reported because the nation failed to carry out its responsibilities for reporting to ensure collection of such information.

Responses to public comments received on the proposed rule are found below.

Changes From the Proposed Rule

The final rule includes minor clarifications to procedures that apply when a nation fails to receive a positive certification under the Act. First, NMFS makes minor revisions to documentation requirements. Current regulations at 50 CFR 300.205(b)(2), 300.206(c), and 300.207(c) refer to ''documentation of admissibility'' that must be ''executed'' by a duly authorized official of an identified nation when fish or fish products are imported into the United States. In an effort to use language that is more clearly understood, this final rule replaces the word ''executed'' with ''properly completed and signed.'' To be consistent with the form that will accompany fish and fish products entering the United States for this rulemaking, this final rule changes the term ''documentation'' to ''certification,'' and clarifies that the certification must be signed by the importer of record prior to submission to NMFS. This final rule also includes a reminder that other import documentation requirements may apply in addition to this certification.

Second, the final rule clarifies the roles of the Departments of Treasury and Homeland Security consistent with Treasury Order 100–16. Under 50 CFR 300.205(b)(1) and (b)(4), the Secretary of Commerce is responsible for notifying the public of both the imposition and removal of trade restrictive measures, with the concurrence of the Secretary of State and in cooperation with the Secretary of Treasury. Treasury Order 100–16 provides that the Secretaries of Treasury and Homeland Security share certain responsibilities pertaining to trade restrictive measures. The final rule clarifies that the Secretary of Commerce will issue these notices in cooperation with the Secretaries of Treasury, Homeland Security, and State.

Finally, the rule now includes text from the High Seas Driftnet Fisheries Enforcement Act (16 U.S.C. 1826a) regarding the denial of port privileges. In describing the denial of port privileges, current regulations at 50 CFR 300.204(a) only include text from the High Seas Driftnet Fisheries Enforcement Act regarding the denial of entry of IUU fishing vessels into the navigable waters of the United States. However, the Act also includes a second provision on withholding or revoking clearance of vessels, which NMFS has included in the final rule.

Response to Public Comments

NMFS received 17 public comments on the proposed rule. These comments came from several environmental non-governmental organizations, fishing industry groups, including fish importers, and foreign governments and trade organizations. NMFS did not make changes to the proposed rule in response to comments received, since many of the suggested changes were not consistent with statutory authority or were outside the scope of this rulemaking.

General Comments

NMFS received several comments in support of the proposed regulations. Many commenters suggested that the regulation could help ''level the playing field'' for U.S. fishermen who are competing in a global market against foreign fishermen that are not required to abide by regulations as stringent as those in the United States.

Application of Regulations to Foreign Vessels

Comment 1: One commenter asked NMFS to clarify that the regulation does not apply to U.S. vessels who may have committed minor infractions of domestic fisheries regulations.

Response: NMFS agrees that the final regulation does not apply to U.S. vessels. The Moratorium Protection Act directs the Secretary of Commerce to identify and certify only foreign nations for having vessels engaged in IUU fishing, bycatch of protected living marine resources, and shark catch on the high seas. U.S. fishermen are, however, subject to regulation under other domestic laws, including but not limited to, the Magnuson-Stevens Fishery Conservation and Management Act, the Marine Mammal Protection Act, the Endangered Species Act, and the Lacey Act.

Application of Import Prohibitions

Comment 2: One commenter raised concerns that language in the proposed rule will lead to inconsistent application of the regulations. In particular, the commenter recommended deleting language regarding NMFS taking into account different conditions when making decisions to identify nations for having vessels engaged in shark catch on the high seas if they do not have a comparable regulatory program to the United States. They asserted that NMFS must use standards consistently across all nations to comply with the World Trade Organization (WTO) Agreement.

Response: The Moratorium Protection Act, at 16 U.S.C. 1826k(a)(2)(B), requires that NMFS take into account different conditions when making identification decisions for nations whose vessels engaged in shark catch beyond any national jurisdiction. While NMFS cannot delete this requirement, NMFS is mindful of U.S. obligations under the WTO Agreement when implementing the provisions of the Moratorium Protection Act, and works with the Office of the U.S. Trade Representative to ensure that any actions taken under the Moratorium Protection Act are consistent with these obligations. Agency actions and recommendations under this final rule will be in accordance with U.S. obligations under applicable international law, including the WTO Agreement.

By taking into account different conditions in a nation's fishery, including conditions that could bear on the feasibility and effectiveness of certain bycatch mitigation measures, NMFS considers alternative measures implemented by the nation that are as effective or more effective than those applicable in U.S. fisheries. This flexibility helps to ensure that identification and certification determinations do not result in the imposition of trade-restrictive measures that are arbitrary or unjustifiably discriminatory because they hold a nation to a higher standard than measures applied in U.S. fisheries.

Comment 3: Commenters suggested broadening the scope of potential trade restrictive measures that could be applied to an identified nation that fails to receive a positive certification to, at a minimum, include all fish or fish products from such nation. If verifiable progress is not made by the nation to control the actions of its vessels, they suggested NMFS develop a process to expeditiously broaden the scope of trade restrictions to cover all goods from that nation that are imported into the United States.

Response: The Moratorium Protection Act limits the scope of import prohibitions that can initially be applied to an identified nation that fails to receive a positive certification. For a nation identified for IUU fishing, import prohibitions would be limited to fish and fish products managed under an applicable international fishery agreement. If there is no applicable international fishery agreement, such prohibitions would only apply to fish and fish products caught by vessels engaged in IUU fishing. For a nation identified for either bycatch or shark catch, import prohibitions would be limited to those that address the relevant fishing activities or practices for which such nations were identified in the biennial report.

However, if after six months following the imposition of import prohibitions

the Secretary of Commerce certifies to the President that the prohibitions are insufficient to cause a nation to effectively address such IUU fishing activity, bycatch, or shark catch or that the nation has taken retaliatory action against the United States, the President may (under authority of the Pelly Amendment at 22 U.S.C. 1978a) direct the Secretary of the Treasury to prohibit the bringing or the importation into the United States of any products from the nation for any duration as the President determines appropriate and to the extent that such prohibition is sanctioned by the WTO.

Comment 4: Another commenter suggested the regulation make it clear that, in the case of an identified nation that fails to receive a positive certification, trade restrictive measures can be applied to all fisheries that are managed under the applicable regional fishery management organization (RFMO), regardless of whether catch of such fish triggered the nation's identification. They specifically requested the deletion of the following statement: ''Such recommendation would address the relevant fishing activities or practices for which such nations were identified in the biennial report,'' since they believe it could be misinterpreted to further limit the scope of potential sanctions by referring only to the fishing activities that give rise to the IUU violations.

Response: NMFS believes the current language does not unduly limit the scope of import prohibitions that can be put into place. Rather, the language ensures that any recommendations for import prohibitions will help address the activities for which the nation was identified. Under the Moratorium Protection Act, if an identified nation fails to receive a positive certification, import prohibitions may potentially be applied to fish and fish products managed under the applicable international fishery agreement.

Comment 5: One commenter was concerned that the proposed regulation does not specify which types of fish and fishing products could face market entry restrictions and raised concerns that the application of trade restrictive measures could be contrary to the spirit of international trade.

Response: The Moratorium Protection Act limits the scope of import prohibitions that can be applied, but does not specify which fisheries products would be prohibited from importation into the United States. This final regulation requires that the Secretary of Commerce recommend the imposition of import prohibitions with respect to fish and fish products associated with the fishing activity that served as the basis for the nation's identification. The regulation further provides that recommended import prohibitions be in accordance with U.S. obligations under applicable international trade law, including the WTO Agreement.

Traceability of Fisheries Products

Comment 6: A few commenters suggested that NMFS and other governmental agencies continue to work towards traceability of imported fisheries products to monitor fisheries products coming into the United States and help implement the provisions of the Moratorium Protection Act.

Response: NMFS agrees. However, establishment of a broad traceability program for all fisheries products is beyond the scope of this rulemaking. Nonetheless, NMFS has taken steps under the Moratorium Protection Act and other laws to improve traceability of fisheries products. With respect to this rulemaking, if import prohibitions are put in place for an identified nation that has failed to receive a positive certification under the Moratorium Protection Act, fish and fish products from the identified nation entering the United States must be accompanied by a completed certification of admissibility available from NMFS. The certification of admissibility must be properly completed and signed by a duly authorized official of the identified nation. The certification must also be signed by the importer of record and submitted to NMFS in a format (electronic facsimile (fax), the Internet, etc.) specified by NMFS for validation.

To assist with the traceability of imported fisheries products, NMFS has implemented several import monitoring programs under other authorities. These include the Tuna Tracking and Verification Program (NOAA Form 370—Fisheries Certificate of Origin) implemented under the Dolphin Protection Consumer Information Act and Marine Mammal Protection Act. This program ensures that imported tuna products are correctly labeled as ''dolphin-safe.'' Similarly, we have implemented a bluefin tuna catch documentation scheme (now a paper-based system, but moving in 2013 to an electronic tracking system) pursuant to U.S. obligations as a Contracting Party to the International Convention for the Conservation of Atlantic Tunas (ICCAT) and under the authority of the Atlantic Tunas Convention Act (ATCA). ICCAT also has swordfish and bigeye tuna statistical document programs that are implemented under ATCA authority. NMFS has also implemented an Antarctic toothfish import monitoring program which requires a catch certificate and pre-approval for imports under the authority of the Antarctic Marine Living Resources Conservation Act.

Comment 7: One commenter encouraged NMFS to communicate the requirements of the Moratorium Protection Act proactively and as quickly as possible to the international community to ensure knowledge of the regulation and its implications.

Response: NMFS agrees and has widely shared information on the provisions of the Moratorium Protection Act with foreign governments at every opportunity, including meetings of RFMOs, the Food and Agriculture Organization of the United Nations (FAO), and other international fora, as appropriate. NMFS has also provided information to many countries during bilateral meetings and through the U.S. State Department.

Verification of Information

Comment 8: One commenter expressed concern that information could be used as the basis for a nation's identification even if the information is not credible and is intended to harm a particular nation.

Response: NMFS makes every effort to validate allegations that a nation's vessels are engaged in fishing activities that could form the basis of identification under the Moratorium Protection Act. Nations are provided an opportunity to address such information before identification decisions are made.

Subsidies for Illegal Fishing

Comment 9: One commenter suggested that when identifying nations, NMFS must identify nations that subsidize illegal fishing.

Response: NMFS does not have authority under the statute to address fishing subsidies. However, the United States fully participates in international negotiations to eliminate harmful fishing subsidies, including the subsidization of vessels identified as having engaged in IUU fishing.

Shark Provisions

Comment 10: One commenter suggested that when identifying nations, NMFS take a strong stance in specifying requirements for shark conservation measures when looking at a nation's comparable regulatory program.

Response: NMFS agrees that strong shark measures must be adopted domestically and strives to help ensure compliance with measures that are adopted internationally. NMFS will be taking a comprehensive look at each

nation's domestic regulatory program for sharks when determining whether that nation's regulatory program is comparable to the United States, taking into account different conditions.

Comment 11: One commenter suggested that NMFS amend the regulation so that it applies to shark catch in waters under national jurisdiction, as well as shark catch on the high seas.

Response: The Moratorium Protection Act, as amended by the Shark Conservation Act, only authorizes NMFS to identify nations for having vessels engaged shark catch beyond any national jurisdiction. Expanding the criteria for shark catch identifications to areas within any national jurisdiction would be outside the scope of the statute. However, shark fishing activity that occurs in another nation's waters could be a basis for identification as IUU fishing if such activity violates a conservation and management measure required under an international fishery management agreement to which the United States is a party.

Comment 12: One commenter suggested removing text allowing NMFS to take into account relevant matters, including, but not limited to, the history, nature, circumstances, and gravity of the fishing activities that target or incidentally catch sharks beyond any national jurisdiction, when making identification decisions. The commenter is concerned that the language provides a loophole that could be used as a basis for not identifying nations that are harvesting and not sustainably managing shark species.

Response: The purpose of the language in the proposed rule is to acknowledge different circumstances that may lead to a nation's identification. The language provides discretion for practicable implementation of the law and allows NMFS to consider all relevant circumstances, such as whether a nation has repeatedly engaged in fishing activities of concern, when making identification decisions.

Comment 13: Several commenters suggested that NMFS examine the use of circle hooks by a nation identified for having vessels engaged in shark catch on the high seas when determining whether to issue a positive certification.

Response: When issuing a certification decision for a nation identified for having vessels engaged in shark catch on the high seas, when appropriate, NMFS will consider, among other things, whether circle hooks are required for U.S. fishermen in the same or similar fisheries, and determine whether the nation has measures in place that are comparable in effectiveness to those required in U.S. fisheries. NMFS will not mandate use of circle hooks in pelagic longline fisheries for shark certifications because such measures are not currently required in U.S. fisheries to mitigate shark bycatch, and may in fact increase shark mortality in some cases.

Comment 14: A commenter expressed concern that U.S. domestic regulations have not been proposed that would implement the requirement that U.S. fishermen must land sharks with their fins naturally attached. The commenter urged NMFS to move forward and issue implementing U.S. regulations immediately.

Response: These regulations only implement provisions of the Shark Conservation Act that amended the Moratorium Protection Act. NMFS will address the domestic fisheries provisions of the Act in separate rulemakings.

Comment 15: Several commenters suggested that NMFS encourage other nations to adopt a National Plan of Action for Sharks.

Response: The United States continues to encourage other nations to adopt and implement a National Plan of Action for Sharks.

Comment 16: When determining whether a nation has a comparable regulatory program to the United States, several commenters suggested that NMFS investigate whether the nation has domestic legislation to implement international requirements and their National Plan of Action for Sharks, as well as effective enforcement.

Response: If NMFS obtains information that a nation has vessels engaged in shark catch on the high seas, we will holistically examine that nation's regulatory program for sharks to determine if it is comparable to that of the United States, including domestic legislation and enforcement of the program. NMFS agrees that these issues are a critical part of a regulatory program and they will be considered.

Comment 17: One commenter discussed their opposition to state finning bans that are being considered for possible adoption.

Response: NMFS cannot address state finning bans in this rulemaking.

Proposed Changes to the IUU Fishing Definition

Comment 18: One commenter suggested that the goal of the proposed regulation is to address stateless vessels in the world's oceans that are not abiding by rules applicable to the U.S. fishermen are subject to. Therefore, they would like the IUU fishing definition amended to include stateless vessels that are engaged in IUU fishing.

Response: The Moratorium Protection Act authorizes NMFS to identify nations for having vessels engaged in IUU fishing, bycatch of protected living marine resources, and shark catch beyond any national jurisdiction. The fishing activities of stateless vessels cannot be addressed under the Moratorium Protection Act. IUU fishing activities by stateless vessels can be addressed pursuant to provisions of a number of international instruments, including the FAO Port State Measures Agreement, which will require the denial of access to ports and/or the withholding of port services to IUU vessels, including stateless vessels.

Comment 19: Several commenters suggested that the definition of IUU fishing be identical to the characterization of IUU fishing that was included in the FAO Port State Measures Agreement. This characterization of IUU fishing refers to the activities set out in paragraph three of the 2001 FAO International Plan of Action to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing (see *http://www.fao.org/docrep/003/y1224e/y1224e00.htm*).

Response: The Moratorium Protection Act sets forth the minimum elements that must be included in the definition of IUU fishing for purposes of the Act. The characterization of IUU fishing that was included in the FAO Port State Measures Agreement serves a different purpose than the definition of IUU fishing for purposes of the Moratorium Protection Act. Under the FAO Port State Measures Agreement, States and other entities commit to adopt measures to strengthen their ports against IUU fisheries products and to enhance port State measures through flag State control. Thus, the characterization of activities that can be considered IUU fishing under the FAO Port State Measures Agreement is broad enough to address specific fishing activities by individual vessels. In contrast, the Moratorium Protection Act provides authority to identify and certify nations for having vessels engaged in IUU fishing, which is defined based on statutory guidelines. For example, the fishing activities of stateless vessels, which are addressed under the Port State Measures Agreement, cannot be addressed under the Moratorium Protection Act, which establishes a process to identify and certify nations, rather than nations' vessels, to promote sustainable fishing activities by their vessels.

In addition, NMFS is not expanding the IUU fishing definition in this final

rule to encompass RFMOs to which the United States is not a member because it could result in a nation's identification for violations of international measures to which the United States is not bound, and was not involved in developing.

IUU Fishing Definition as It Addresses Impacts to Vulnerable Marine Ecosystems

Comment 20: Several commenters expressed concern about the aspect of the IUU fishing definition that pertains to fishing activities that adversely impact vulnerable marine ecosystems (VMEs). Specifically, they requested that NMFS delete the term ''significant'' before ''adverse impact,'' so that the VME aspect of the IUU fishing definition can be interpreted more broadly.

Response: In the current regulations, NMFS harmonized the applicable section of the IUU definition to be consistent with international norms of the United Nations General Assembly and FAO. NMFS added ''significant'' before ''adverse impact'' in the definition to reflect the standard of significant adverse impact as established in United Nations General Assembly Resolutions 61/105, 64/72, and 66/88, as well as the FAO International Guidelines for the Management of Deep-sea Fisheries in the High Seas.

Classification

This final rule is published under the authority of the Moratorium Protection Act, 16 U.S.C. 1826d–1826k, as amended by the Shark Conservation Act (Pub. L. 111–348).

This rulemaking has been determined to be significant for the purposes of Executive Order 12866.

Pursuant to 5 U.S.C. 553(d)(3), NOAA finds that there is good cause to waive the 30-day delay in the effective date of this rule. This rule is procedural in nature: It only creates procedures for the agency to follow when determining the identification and certification of nations whose fishing vessels are engaged in shark catch beyond any national jurisdiction. Importantly, the rule does not modify, add, or revoke any existing rights and obligations of the public or any private parties, because the rule only applies to NOAA. Once this final rule is implemented, the public is not required to take any action to come into compliance. Accordingly, NOAA finds that there is good cause, within the meaning of 5 U.S.C. 553(d)(3), to waive the 30-day delay in effectiveness of this rule and to make this rule effective immediately.

Pursuant to section 605 of the Regulatory Flexibility Act, at the proposed rule stage, the Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that this final rule would not have a significant economic impact on a substantial number of small entities. NMFS did not receive any comments on that certification. For any questions about the certification, please contact NMFS at the contact provided under **FOR FURTHER INFORMATION**.

This final rule contains collection-of-information requirements for §§ 300.206(b)(2), 300.207(c), and 300.208(c) subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The collection-of-information requirements have been approved by OMB under control number 0648–0651.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Bycatch, Exports, Fish, Fisheries, Fishing, Imports, IUU Fishing, Marine resources, Reporting and recordkeeping requirements, Sharks, Treaties, Wildlife.

Dated: January 10, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs.

For the reasons set out in the preamble, 50 CFR part 300 is amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for part 300 continues to read as follows:

Authority: Moratorium Protection Act, 16 U.S.C. 1826d–1826k.

■ 2. Section 300.200 is revised to read as follows:

§ 300.200 Purpose and scope.

The purpose of this subpart is to implement the requirements in the High Seas Driftnet Fishing Moratorium Protection Act (''Moratorium Protection Act'') to identify and certify nations whose vessels engaged in illegal, unreported, or unregulated fishing; whose fishing activities result in bycatch of protected living marine resources; or whose vessels engaged in fishing activities or practices on the high seas that target or incidentally catch sharks where the nation has not adopted a regulatory program for the conservation of sharks, comparable in effectiveness to that of the United States, taking into account different conditions. This language applies to vessels entitled to fly the flag of the nation in question. Where the Secretary of Commerce determines that an identified nation has not taken the necessary actions to warrant receipt of a positive certification, the Secretary of Commerce may recommend to the President that the United States prohibit the importation of certain fish and fish products from the identified nation or other measures. The Secretary of Commerce will recommend to the President appropriate measures, including trade restrictive measures, to be taken against identified nations that have not received a positive certification, to address the fishing activities or practices for which such nations were identified in the biennial report. The Secretary of Commerce will make such a recommendation on a case-by-case basis in accordance with international obligations, including the World Trade Organization (WTO) Agreement. The Moratorium Protection Act also authorizes cooperation and assistance to nations to take action to combat illegal, unreported, or unregulated fishing, reduce bycatch of protected living marine resources, and achieve shark conservation.

■ 3. In § 300.201, the definition of ''Illegal, unreported, or unregulated (IUU) fishing'' is revised to read as follows:

§ 300.201 Definitions.

* * * * *

Illegal, unreported, or unregulated (IUU) fishing means:

(1) In the case of parties to an international fishery management agreement to which the United States is a party, fishing activities that violate conservation and management measures required under an international fishery management agreement to which the United States is a party, including but not limited to catch limits or quotas, capacity restrictions, bycatch reduction requirements, shark conservation measures, and data reporting;

(2) In the case of non-parties to an international fishery management agreement to which the United States is a party, fishing activities that would undermine the conservation of the resources managed under that agreement;

(3) Overfishing of fish stocks shared by the United States, for which there are no applicable international conservation or management measures, or in areas with no applicable international fishery management organization or agreement,

that has adverse impacts on such stocks; or,

(4) Fishing activity that has a significant adverse impact on seamounts, hydrothermal vents, cold water corals and other vulnerable marine ecosystems located beyond any national jurisdiction, for which there are no applicable conservation or management measures or in areas with no applicable international fishery management organization or agreement.

(5) Fishing activities by foreign flagged vessels in U.S. waters without authorization of the United States.

* * * * *

■ 4. In § 300.202, paragraphs (a)(2) and (d)(1) are revised to read as follows:

§ 300.202 Identification and certification of nations engaged in illegal, unreported, or unregulated fishing activities.

(a) * * *

(2) When determining whether to identify a nation as having fishing vessels engaged in IUU fishing, NMFS will take into account all relevant matters, including but not limited to the history, nature, circumstances, extent, duration, and gravity of the IUU fishing activity in question, and any measures that the nation has implemented to address the IUU fishing activity. NMFS will also take into account whether an international fishery management organization exists with a mandate to regulate the fishery in which the IUU activity in question takes place. If such an organization exists, NMFS will consider whether the relevant international fishery management organization has adopted measures that are effective at addressing the IUU fishing activity in question and, if the nation whose fishing vessels are engaged, or have been engaged, in IUU fishing is a party to, or maintains cooperating status with, the organization. NMFS will also take into account any actions taken or on-going proceedings by the United States and/or flag State to address the IUU fishing activity of concern as well as the effectiveness of such actions.

* * * * *

(d) * * *

(1) The Secretary of Commerce shall issue a positive certification to an identified nation upon making a determination that such nation has taken appropriate corrective action to address the activities for which such nation has been identified in the biennial report to Congress. When making such determination, the Secretary shall take into account the following:

(i) Whether the government of the nation identified pursuant to paragraph (a) of this section has provided evidence documenting that it has taken corrective action to address the IUU fishing activity described in the biennial report;

(ii) Whether the relevant international fishery management organization has adopted and, if applicable, the identified member nation has implemented and is enforcing, measures to effectively address the IUU fishing activity of the identified nation's fishing vessels described in the biennial report;

(iii) Whether the United States has taken enforcement action to effectively address the IUU fishing activity of the identified nation described in the biennial report; and

(iv) Whether the identified nation has cooperated in any action taken by the United States to address the IUU fishing activity described in the biennial report.

* * * * *

■ 5. In 300.203, paragraphs (a)(1), (a)(2), and (c)(1) are revised; paragraph (c)(2) is redesignated as paragraph (c)(3), and a new paragraph (c)(2) is added to read as follows:

§ 300.203 Identification and certification of nations engaged in bycatch of protected living marine resources.

(a) * * *

(1) NMFS will identify and list, in the biennial report to Congress nations—

(i) whose fishing vessels are engaged, or have been engaged during the preceding calendar year prior to publication of the biennial report to Congress, in fishing activities or practices either in waters beyond any national jurisdiction that result in bycatch of a PLMR, or in waters beyond the U.S. EEZ that result in bycatch of a PLMR that is shared by the United States;

(ii) if the nation is a party to or maintains cooperating status with the relevant international organization with jurisdiction over the conservation and protection of the relevant PLMRs, or a relevant international or regional fishery organization, and the organization has not adopted measures to effectively end or reduce bycatch of such species; and

(iii) the nation has not implemented measures designed to end or reduce such bycatch that are comparable in effectiveness to U.S. regulatory requirements, taking into account different conditions that could bear on the feasibility and efficacy of comparable measures.

(2) When determining whether to identify nations as having fishing vessels engaged in PLMR bycatch, NMFS will take into account all relevant matters including, but not limited to, the history, nature, circumstances, extent, duration, and gravity of the bycatch activity in question.

* * * * *

(c) * * *

(1) Initiate consultations within 60 days after submission of the biennial report to Congress with the governments of identified nations for the purposes of encouraging adoption of a regulatory program for protected living marine resources that is comparable in effectiveness to that of the United States, taking into account different conditions, and establishment of a management plan that assists in the collection of species-specific data;

(2) Seek to enter into bilateral and multilateral treaties with such nations to protect the PLMRs from bycatch activities described in the biennial report; and

* * * * *

§§ 300.204, 300.205, 300.206, and 300.207 [Redesignated as §§ 300.205, 300.206, and 300.207, 300.208]

■ 6a. Sections 300.204, 300.205, 300.206, and 300.207 are redesignated as §§ 300.205, 300.206, and 300.207, 300.208, respectively.

■ 6b. A new § 300.204 is added to read as follows:

§ 300.204 Identification and certification of nations whose vessels are engaged in shark catch.

(a) Procedures to identify nations if fishing vessels of that nation are engaged in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks during the preceding calendar year.—(1) NMFS will identify and list in the biennial report to Congress nations—

(i) Whose fishing vessels are engaged, or have been engaged during the calendar year prior to publication of the biennial report to Congress, in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks; and

(ii) Where that nation has not adopted a regulatory program to provide for the conservation of sharks, including measures to prohibit removal of any of the fins of a shark (including the tail) and discard the carcass of the shark at sea, that is comparable in effectiveness to that of the United States, taking into account different conditions, including conditions that could bear on the feasibility and effectiveness of measures.

(2) When determining whether to identify nations for these activities, NMFS will take into account all relevant matters including, but not limited to, the history, nature, circumstances,

duration, and gravity of the fishing activity of concern.

(b) *Notification of nations identified as having fishing vessels engaged in fishing activities or practices that target or incidentally catch sharks.* Upon identifying in the biennial report to Congress a nation whose vessels engaged in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks, the Secretary of Commerce will notify the President of such identification. Within 60 days after submission of the biennial report to Congress, the Secretary of Commerce, acting through or in consultation with the Secretary of State, will notify identified nations about the requirements under the Moratorium Protection Act and this subpart N.

(c) *Consultations and negotiations.* Upon submission of the biennial report to Congress, the Secretary of Commerce, acting through or in consultation with the Secretary of State, will:

(1) Initiate consultations within 60 days after submission of the biennial report to Congress with the governments of identified nations for the purposes of encouraging adoption of a regulatory program for the conservation of sharks that is comparable in effectiveness to that of the United States, taking into account different conditions, and establishment of a management plan that assists in the collection of species-specific data;

(2) Seek to enter into bilateral and multilateral treaties or other arrangements with such nations to protect sharks; and

(3) Seek agreements through the appropriate international organizations calling for international restrictions on the fishing activities or practices described in the biennial report and, as necessary, request the Secretary of State to initiate the amendment of any existing international treaty to which the United States is a party for the conservation of sharks to make such agreements consistent with this subpart.

(d) *International Cooperation and Assistance.* To the greatest extent possible, consistent with existing authority and the availability of funds, the Secretary shall:

(1) Provide appropriate assistance to nations identified by the Secretary under paragraph (a) of this section and international organizations of which those nations are members to assist those nations in qualifying for a positive certification under paragraph (e) of this section;

(2) Undertake, where appropriate, cooperative research activities on species assessments and harvesting techniques aimed at mitigating or eliminating the non-target catch of sharks, with those nations or organizations;

(3) Encourage and facilitate the transfer of appropriate technology to those nations or organizations to assist those nations in qualifying for positive certification under paragraph (e) of this section; and

(4) Provide assistance to those nations or organizations in designing, implementing, and enforcing appropriate fish harvesting plans for the conservation and sustainable management of sharks.

(e) *Procedures to certify nations identified as having fishing vessels engaged in fishing activities or practices that target or incidentally catch sharks.* Each nation that is identified as having fishing vessels engaged in fishing activities or practices in waters beyond any national jurisdiction that target or incidentally catch sharks and has not adopted a regulatory program for the conservation of sharks, including measures to prohibit removal of any of the fins of a shark (including the tail) and discard the carcass of the shark at sea, that is comparable to that of the United States, taking into account different conditions, shall receive either a positive or a negative certification from the Secretary of Commerce. This certification will be published in the biennial report to Congress. The Secretary of Commerce shall issue a positive certification to an identified nation upon making a determination that:

(1) Such nation has provided evidence documenting its adoption of a regulatory program for the conservation of sharks that is comparable in effectiveness to regulatory measures required under U.S. law in the relevant fisheries, taking into account different conditions, including conditions that could bear on the feasibility and effectiveness of measures; and such nation has established a management plan that will assist in the collection of species-specific data on sharks to support international stock assessments and conservation efforts for sharks.

(2) Prior to a formal certification determination, nations will be provided with preliminary certification determinations, and an opportunity to support and/or refute the preliminary determinations, and communicate actions taken to adopt a regulatory program that is comparable in effectiveness to that of the United States, taking into account different conditions. The Secretary of Commerce shall consider any relevant information received during consultations when making its formal certification determination.

■ 7. Newly redesignated § 300.205 is revised to read as follows:

§ 300.205 Effect of certification.

(a) If a nation identified under § 300.202(a), § 300.203(a), or § 300.204(a) does not receive a positive certification under this subpart (*i.e.,* the nation receives a negative certification or no certification is made), the Secretary of Treasury shall, in accordance with recognized principles of international law:

(1) Withhold or revoke the clearance required by section 91 of the Appendix to Title 46 for the fishing vessels of such nation; and

(2) Deny entry to the fishing vessels of such nation to any place in the United States and to the navigable waters of the United States.

(b) Upon notification and any recommendations by the Secretary of Commerce to the President that an identified nation has failed to receive a positive certification, the President is authorized to direct the Secretary of the Treasury to prohibit the importation of certain fish and fish products from such nation (see § 300.206).

(c) Any action recommended under paragraph (b) of this section shall be consistent with international obligations, including the WTO Agreement.

(d) If certain fish and fish products are prohibited from entering the United States, within six months after the imposition of the prohibition, the Secretary of Commerce shall determine whether the prohibition is insufficient to cause that nation to effectively address the IUU fishing, bycatch, or shark catch described in the biennial report, or that nation has retaliated against the United States as a result of that prohibition. The Secretary of Commerce shall certify to the President each affirmative determination that an import prohibition is insufficient to cause a nation to effectively address such IUU fishing activity, bycatch, or shark catch or that a nation has taken retaliatory action against the United States. This certification is deemed to be a certification under section 1978(a) of Title 22, which provides that the President may direct the Secretary of the Treasury to prohibit the bringing or the importation into the United States of any products from the offending country for any duration as the President determines appropriate and to the extent that such prohibition is sanctioned by the World Trade Organization.

(e) *Duration of certification.* Any nation identified in the biennial report to Congress for having vessels engaged in IUU fishing that is negatively certified will remain negatively certified until the Secretary of Commerce determines that the nation has taken appropriate corrective action to address the IUU fishing activities for which it was identified in the biennial report. Any nation identified in the biennial report to Congress for having vessels engaged in PLMR bycatch or catch of sharks that is negatively certified will remain negatively certified until the Secretary of Commerce determines that the nation has taken the necessary actions pursuant to the Moratorium Protection Act to receive a positive certification.

(f) *Consultations.* NMFS will, working through or in consultation with the Department of State, continue consultations with nations that do not receive a positive certification with respect to the fishing activities described in the biennial report to Congress. The Secretary of Commerce shall take the results of such consultations into consideration when making a subsequent certification determination for each such nation.

■ 8. In newly redesignated § 300.206, revise paragraphs (a)(1) through (3) and (b)(1), (2) and (4) to read as follows:

§ 300.206 Denial of port privileges and import restrictions on fish or fish products.

(a) * * *

(1) Vessels from a nation identified in the biennial report under § 300.202(a), § 300.203(a), or § 300.204(a) and not positively certified by the Secretary of Commerce that enter any place in the United States or the navigable waters of the United States remain subject to inspection and may be prohibited from landing, processing, or transshipping fish and fish products, under applicable law. Services, including the refueling and re-supplying of such fishing vessels, may be prohibited, with the exception of services essential to the safety, health, and welfare of the crew. Fishing vessels will not be denied port access or services in cases of force majeure or distress.

(2) For nations identified in the previous biennial report under § 300.202(a) that are not positively certified in the current biennial report, the Secretary of Commerce shall so notify and make recommendations to the President, who is authorized to direct the Secretary of Treasury to impose import prohibitions with respect to fish and fish products from those nations. Such a recommendation would address the relevant fishing activities or practices for which such nations were identified in the biennial report. Such import prohibitions, if implemented, would apply to fish and fish products managed under an applicable international fishery agreement. If there is no applicable international fishery agreement, such prohibitions, if implemented, would only apply to fish and fish products caught by vessels engaged in illegal, unreported, or unregulated fishing. For nations identified under § 300.203(a) or § 300.204(a) that are not positively certified, the Secretary of Commerce shall so notify and make recommendations to the President, who is authorized to direct the Secretary of Treasury to impose import prohibitions with respect to fish and fish products from those nations; such prohibitions would only apply to fish and fish products caught by the vessels engaged in the relevant activity for which the nation was identified.

(3) Any action recommended under paragraph (a)(2) shall be consistent with international obligations, including the WTO Agreement.

(b) * * *

(1) *Notification.* Where the Secretary of Commerce cannot make positive certifications for identified nations, and the President determines that certain fish and fish products from such nations are ineligible for entry into the United States and U.S. territories, the Secretary of Commerce, in cooperation with the Secretaries of Treasury, Homeland Security, and State, will file a notice with the Office of the Federal Register.

(2) *Certification of admissibility.* If certain fish or fish products are subject to import prohibitions, NMFS may publish in the **Federal Register** the requirement that, in addition to any other import documentation requirements that otherwise apply, other fish or fish products from the relevant nation, that are not subject to the prohibitions, offered for entry under this section must be accompanied by certification of admissibility, for which a form is available from NMFS. The certification of admissibility must be properly completed and signed by a duly authorized official of the identified nation and validated by a responsible official(s) designated by NMFS. The certification must be signed by the importer of record and submitted to NMFS in a format (electronic facsimile (fax), the Internet, etc.) specified by NMFS.

* * * * *

(4) *Removal of negative certifications and import restrictions.* Upon a determination by the Secretary of Commerce that an identified nation that was not certified positively has satisfactorily met the conditions in this subpart and that nation has been positively certified, the provisions of § 300.206 shall no longer apply. The Secretary of Commerce, in cooperation with the Secretaries of Treasury, Homeland Security, and State, will notify such nations and will file with the Office of the Federal Register for publication notification of the removal of the import restrictions effective on the date of publication.

■ 9. In newly redesignated § 300.207, revise the section heading, and paragraph (c), and add paragraph (d) to read as follows:

§ 300.207 Alternative procedures for nations identified as having vessels engaged in IUU fishing activities that are not certified in this subpart.

* * * * *

(c) In addition to any other import documentation requirements that otherwise apply, fish and fish products offered for entry under this section must be accompanied by certification of admissibility, for which a form is available from NMFS. The certification of admissibility must be properly completed and signed by a duly authorized official of the identified nation and must be validated by a responsible official(s) designated by NMFS. The certification must also be signed by the importer of record and submitted to NMFS in a format (electronic facsimile (fax), the Internet, etc.) specified by NMFS.

(d) Any action recommended under this section shall be consistent with international obligations, including the WTO Agreement.

■ 10. In newly redesignated § 300.208, revise the section heading, and paragraph (c), and add paragraph (d) to read as follows:

§ 300.208 Alternative procedures for nations identified as having vessels engaged in bycatch of PLMRs that are not certified in this subpart.

* * * * *

(c) In addition to any other import documentation requirements that otherwise apply, fish and fish products offered for entry under this section must be accompanied by certification of admissibility, for which a form is available from NMFS. The certification of admissibility must be properly completed and signed by a duly authorized official of the identified nation and must be validated by a responsible official(s) designated by NMFS. The certification must also be signed by the importer of record and

submitted to NMFS in a format (electronic facsimile (fax), the Internet, etc.) specified by NMFS.

(d) Any action recommended under this section shall be consistent with international obligations, including the WTO Agreement.

■ 11. Add § 300.209 to read as follows:

§ 300.209 Alternative procedures for nations identified as having vessels engaged in shark catch that are not certified in this subpart.

(a) These certification procedures may be applied to fish and fish products from a vessel of a harvesting nation that has been identified under § 300.204 in the event that the Secretary cannot reach a certification determination for that nation by the time of the next biennial report. These procedures shall not apply to fish and fish products from identified nations that have received either a negative or a positive certification under this subpart.

(b) Consistent with paragraph (a) of this section, the Secretary of Commerce may allow entry of fish and fish products on a shipment-by-shipment, shipper-by-shipper, or other basis if the Secretary determines that imports were harvested by fishing activities or practices that do not target or incidentally catch sharks, or were harvested by practices that—

(1) Are comparable to those of the United States, taking into account different conditions; and

(2) Include the gathering of species specific shark data that can be used to support international and regional assessments and conservation efforts for sharks.

(c) In addition to any other import documentation requirements that otherwise apply, fish and fish products offered for entry under this section must be accompanied by certification of admissibility, for which a form is available from NMFS. The certification of admissibility must be properly completed and signed by a duly authorized official of the identified nation and validated by a responsible official(s) designated by NMFS. The certification must also be signed by the importer of record and submitted to NMFS in a format (electronic facsimile (fax), the Internet, etc.) specified by NMFS.

(d) Any action recommended under this section shall be consistent with international obligations, including the WTO Agreement.

[FR Doc. 2013–00703 Filed 1–11–13; 11:15 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 120731291–2522–02]

RIN 0648–BC40

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Specifications and Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is implementing 2013–2015 specifications and management measures for Atlantic mackerel, and 2013 specifications for butterfish. Specifications for longfin squid and *Illex* squid were set for 3 years in 2012 (2012–2014) and therefore are not included in this year's specification rulemaking. These final specifications also implement regulatory changes to the longfin squid fishery, the butterfish mortality cap to avoid 1–2 week closures at the end of a Trimester, and the pre-trip observer notification for longfin squid trips landing over 2,500 lb (1.3 mt) from 72 to 48 hr. Compared to 2012, the butterfish domestic annual harvest implemented in this action (2,570 mt) represents an increase of 1,698 mt over the 2012 domestic annual harvest (872 mt). The butterfish mortality cap implemented in this action (4,464 mt) represents an increase of 1,299-mt over the current 2012 cap level (3,165 mt). Due to the increase in the proposed butterfish quota, this action also implements a variety of management measures for controlling effort in the directed butterfish fishery, including changes to trip limits, the closure threshold for the directed fishery, and post-closure trip limits. Finally, this rule implements minor corrections to existing regulatory text, to clarify the intent of the regulations. These specifications and management measures promote the utilization and conservation of the Atlantic mackerel, squid, and butterfish resource.

DATES: Effective January 16, 2013, except for the amendments to § 648.27, which will be effective on February 15, 2013.

ADDRESSES: Copies of the 2013 specifications document, including the Environmental Assessment (EA), is available from John K. Bullard, Northeast Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. This document is also accessible via the Internet at *http://www.nero.noaa.gov.* NMFS prepared a Final Regulatory Flexibility Analysis (FRFA), which is contained in the Classification section of this rule. Copies of the FRFA and the Small Entity Compliance Guide are available from: John K. Bullard, Regional Administrator, National Marine Fisheries Service, Northeast Region, 55 Great Republic Drive, Gloucester, MA 01930–2276, or via the internet at *http://www.nero.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Lindsey Feldman, Fishery Management Specialist, 978–675–2179, fax 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

Specifications, as referred to in this rule, are the combined suite of commercial and recreational catch levels established for 1 or more fishing years. The specification process also allows for the modification of a select number of management measures, such as closure thresholds, gear restrictions, and possession limits. The Mid-Atlantic Fishery Management Council's (Council) process for establishing specifications relies on provisions within the Atlantic Mackerel, Squid, and Butterfish (MSB) Fishery Management Plan (FMP) and its implementing regulations, as well as requirements established by the Magnuson–Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Specifically, section 302(g)(1)(B) of the Magnuson-Stevens Act states that the Scientific and Statistical Committee (SSC) for each Regional Fishery Management Council shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch (ABC), preventing overfishing, maximum sustainable yield, and achieving rebuilding targets. The ABC is a level of catch that accounts for the scientific uncertainty in the estimate of the stock's defined overfishing level (OFL).

The Council's SSC met on May 23 and 24, 2012, confirming 2013 specifications for *Illex* and longfin squid and recommending ABCs for the 2013–2015 Atlantic mackerel (mackerel) and 2013 butterfish specifications. A proposed rule for 2013 MSB specifications and management measures was published on November 19, 2012 (77 FR 69426), and the public comment period for the

proposed rule ended on December 10, 2012.

The MSB regulations require the specification of annual catch limits (ACL) and accountability measures (AM) for mackerel and butterfish (both squid species are exempt from the ACL/AM requirements because they have a life cycle of less than 1 year). In addition, the regulations require the specification of domestic annual harvest (DAH), domestic annual processing (DAP), and total allowable level of foreign fishing (TALFF), along with joint venture processing for (JVP) commercial and recreational annual catch totals (ACT) for mackerel, the butterfish mortality cap in the longfin squid fishery, and initial optimum yield (IOY) for both squid species. Details concerning the Council's development of these measures were presented in the preamble of the proposed rule and are not repeated here.

Research Set-Aside

The Mid-Atlantic Research Set-Aside (RSA) Program funds research projects through the sale of fish that has been set aside from the total annual quota. The RSA may vary between 0 and 3 percent of the overall quota for each species. NMFS solicited research proposals under the 2013 Mid-Atlantic RSA Program through a Federal Funding Opportunity announcement that published on February 17, 2012 (Funding Opportunity Number NOAA–NMFS–NEFSC–2013–2003258 on *grants.gov*). Two projects were preliminarily selected by NMFS, although final grant approval by NOAA Grants is pending. Federally permitted vessels harvesting RSA quota are issued Exempted Fishing Permits in support of approved research projects, which would authorize them to exceed Federal possession limits and to fish during Federal quota closures. If approved, the projects would be awarded 589,800 lb (267,529 kg) of summer flounder, 958,950 lb (434,972 kg) of scup, 111,900 lb (50,757 kg) of black sea bass, 874,000 lb (396,440 kg) of longfin squid, 79,455 lb (36,040 kg) of butterfish for discards on longfin squid research trips, and 715,830 lb (324,695 kg) of bluefish. The research projects preliminary selected include the following:

- A near-shore trawl survey between Martha's Vineyard, MA, and Cape Hatteras, NC, in shallow waters unsampled by current Federal finfish bottom trawl surveys to provide stock assessment data for Mid-Atlantic RSA species, including summer flounder, scup, black sea bass, longfin squid, butterfish, and Atlantic bluefish, and assessment-quality data for weakfish, Atlantic croaker, spot, several skate and ray species, smooth dogfish, horseshoe crab, and several unmanaged but important forage species; and
- A fishery-independent black sea bass survey of four separate hard-bottom sites unsampled by current state and Federal finfish bottom trawl surveys in southern New England and Mid-Atlantic waters using unvented black sea bass pots.

The Council recommended that up to 3 percent of the total ACL for mackerel, up to 3 percent of the IOY for *Illex* and longfin squid, and up to 2 percent of the butterfish ACT could be set aside to fund projects selected under the 2013 Mid-Atlantic RSA Program, where 59 mt could be set aside for butterfish discard on longfin squid research trips, and 151 mt could be set aside for directed butterfish landings. The final RSA awards are subtracted from the IOY for longfin squid, and the butterfish mortality cap in Table 1 below.

TABLE 1—FINAL SPECIFICATIONS, IN METRIC TONS (MT), FOR MACKEREL FOR 2013–2015, BUTTERFISH FOR 2013, AND LONGFIN AND ILLEX SQUID FOR THE 2013–2014 FISHING YEAR

Specifications	Mackerel	Butterfish	*Illex*	Longfin
OFL	Unknown	Unknown	Unknown	Unknown
ABC	43,781	8,400	24,000	23,400
ACL	43,781	7,560	N/A	N/A
Commercial ACT	34,907	7,560	N/A	N/A
Recreational ACT/RHL	2,443	N/A	N/A	N/A
IOY	N/A	N/A	22,915	22,049
DAH/DAP	33,821	2,570	22,915	22,049
JVP	0	N/A	N/A	N/A
TALFF	0	0	N/A	N/A
RSA	N/A	36	N/A	396
Butterfish Mortality Cap		4,464		

Final 2013–2015 Specifications and Management Measures for Mackerel

This action specifies the mackerel U.S. ABC at 43,781 mt. The status of the mackerel stock was assessed by the Transboundary Resources Assessment Committee (TRAC) in March 2010. The 2010 TRAC Status Report indicated reduced productivity in the stock and a lack of older fish in both the survey and catch data, and determined that the status of the mackerel stock is unknown because biomass reference points could not be determined. Due to uncertainty in the assessment, the TRAC recommended that total annual catches not exceed 80,000 mt (average total U.S. and Canadian landings from 2006–2008) until new information is available. The mackerel stock-wide ABC was set at 80,000 mt for 2012, consistent with the TRAC recommendation. Since a new mackerel assessment is not expected for several years, the SSC recommended maintaining the 2012 mackerel specification and specifying the stock-wide ABC for 3 years (2013–2015) at 80,000 mt. The Council recommended a U.S. ABC of 43,781 mt (80,000 mt—36,219 mt (2010 actual Canadian catch)). Due to the variability in recent Canadian catch, and the inability to predict Canadian catch for 2013, the SSC recommended the use of Canadian catch from 2010 (the same amount used for setting 2012 specifications).

Consistent with MSB Amendment 11, the Council recommended a recreational allocation of 2,714 mt (6.2 percent of the U.S. ABC). The proposed Recreational ACT of 2,443 mt (90 percent of the U.S. ABC of 2,714 mt) was reduced to account for low precision and time lag of recreational catch estimates, as well as lack of recreational discard estimates. The Recreational ACT is equal to the Recreational Harvest Limit (RHL), which would be the effective cap on recreational catch.

For the commercial mackerel fishery, the Council recommended a commercial fishery allocation of 41,067 mt (93.8 percent of the U.S. ABC, the portion of the ACL that was not allocated to the recreational fishery). The recommended

Commercial ACT of 34,907 mt (85 percent of 41,067) was reduced to address uncertainty in estimated 2013 Canadian landings, uncertainty in discard estimates, and possible misreporting. The Commercial ACT was further reduced by a discard rate of 3.11 percent (mean plus one standard deviation of discards from 1999–2008), to arrive at the proposed DAH of 33,821 mt. The DAH was proposed as the effective cap on commercial catch, as it has been in past specifications.

Consistent with the Council's recommendation, this action sets the 2013–2015 mackerel specifications so that the U.S. ABC/ACL is 43,781 mt; the Commercial ACT is 34,907 mt; the DAH and DAP are 33,821 mt; and the Recreational ACT is 2,443 mt. Additionally, as recommended by the Council, JVP is maintained as zero. There was no mackerel awarded for the RSA program for the 2013 fishing year.

The Magnuson-Stevens Act provides that the specification of TALFF, if any, shall be the portion of the optimum yield (OY) of a fishery that will not be harvested by U.S. vessels. TALFF would allow foreign vessels to harvest U.S. fish and sell their product on the world market, in direct competition with U.S. industry efforts to expand exports. While a surplus existed between ABC and the mackerel fleet's harvesting capacity for many years, that surplus has disappeared due to decreases in the specifications in recent years. Based on analysis and a review of the state of the world mackerel market and possible increases in U.S. production levels, the Council concluded that specifying a DAH/DAP resulting in zero TALFF will yield positive social and economic benefits to both U.S. harvesters and processors, and to the Nation. For these reasons, consistent with the Council's recommendation, NMFS is specifying the DAH at a level that can be fully harvested by the domestic fleet, thereby precluding the specification of a TALFF, in order to support the U.S. mackerel industry. NMFS concurs that it is reasonable to assume that in 2013 the commercial mackerel fishery has the ability to harvest 33,821 mt of mackerel.

Final 2013 Specifications and Management Measures for Butterfish

This action specifies the butterfish ABC at 8,400 mt. The current status of the butterfish stock is unknown because biomass reference points could not be determined in the SAW 49 assessment (February 2010); however, survey trends since the most recent assessment suggest an increase in butterfish abundance. In recommending 2013 specifications, the SSC considered multiple sources of information, including a recent analysis of the butterfish stock by Dr. Paul Rago and Dr. Tim Miller from NOAA's Northeast Fisheries Science Center (NEFSC). Because of the uncertainty in the most recent butterfish stock assessment, on April 6, 2012, the Council requested that NEFSC offer additional analysis of the butterfish stock to aid the SSC in the ABC setting process for the 2013 fishing year. The NEFSC analysis (May 2, 2012) applied ranges of a number of different factors (such as natural mortality and survey catchability) to develop a range of likely stock biomasses that would be consistent with recent survey results and observed butterfish catch. The NEFSC also examined a range of fishing mortalities that would result from these biomass estimates. The SSC used the NEFSC analysis, along with guidance (Patterson, 1992) that suggests maintaining a natural mortality/fishing mortality ratio of 67 percent for small pelagic species, to develop a proxy OFL for butterfish. Consistent with the 2010 butterfish assessment, the SSC assumed a high level of natural mortality (M = 0.8) and applied the 67-percent ratio to result in a fishing mortality rate of F = 0.536, which the SSC used as a proxy maximum F threshold for butterfish. In the NEFSC analysis, a catch of 16,800 mt would only lead to fishing mortality rates higher than F = 0.536 (i.e., rates consistent with overfishing based on the maximum fishing mortality rate threshold proxy) under very extreme assumptions. The SSC therefore adopted 16,800 mt as a proxy OFL. The SSC buffered the proxy OFL by 50 percent to reach the butterfish ABC of 8,400 mt. The SSC's justification for this buffer noted that the short life history of butterfish gives limited time for management to respond to adverse patterns, that recruitment of butterfish is highly variable and uncertain, that the stock status of butterfish is unknown, and that butterfish are susceptible to environmental and ecosystem variability, in particular inter-annual variability in natural mortality. A detailed summary of the SSC's rationale for its 2013 butterfish ABC recommendation is available in its May 2012 Report (available, along with other materials from the SSC discussion, at: *http://www.mafmc.org/meeting_materials/SSC/2012-05/SSC_2012_05.htm*).

The Council recommended setting the butterfish ACL equal to the ABC, and establishing a 10-percent buffer between ACL and ACT for management uncertainty, which would result in an ACT of 7,560 mt. Since discards have been roughly ⅔ of catch (1999–2008 average), the Council recommended setting the DAH and DAP at 2,570 mt (7,560 mt − 4,990 mt discards). Since up to 3 percent of the ACL for butterfish may be set aside for scientific research, the Council recommended setting aside 2 percent of the butterfish ACT for research, where 59 mt would be set aside for butterfish discard on longfin squid research trips, and 151 mt would be set aside for directed butterfish landings. RSA projects were not awarded any directed butterfish, but were awarded 36 mt of butterfish to account for discards on longfin squid research trips. After accounting for 36 mt of RSA, the butterfish mortality cap on the longfin squid fishery was revised from 4,500 mt to 4,464 mt (59.05 percent of the ACT of 7,560 mt).

NMFS is implementing butterfish specifications for the 2013 fishing year, consistent with the Council's recommendations, that would set the butterfish ABC/ACL at 8,400 mt, the ACT at 7,560 mt, the DAH and DAP at 2,570 mt, TALFF at zero, and the butterfish mortality cap on the longfin squid fishery at 4,464 mt. Additionally, this action allocates the 2013 butterfish mortality cap by Trimester as follows:

TABLE 2—TRIMESTER ALLOCATION OF BUTTERFISH MORTALITY CAP ON THE LONGFIN SQUID FISHERY FOR 2013

Trimester	Percent	Metric tons
I (Jan–Apr)	65	2,902
II (May–Aug)	3.3	147
III (Sep–Dec)	31.7	1,415
Total	100	4,464

Due to the increase in the recommended butterfish DAH and butterfish mortality cap, a variety of management measures were recommended by the Council to control fishing effort while allowing the expansion of a profitable directed butterfish fishery. The Council recommended, and this action implements, a three-phase management system for the directed butterfish fishery (Table 3) to allow for maximum utilization of the butterfish resource without exceeding the stock-wide ACL.

In phase 1, there is no trip limit for vessels issued longfin squid/butterfish moratorium permits using mesh greater than or equal to 3 inches (7.62 cm), a 2,500-lb (1.13-mt) trip limit for longfin squid/butterfish moratorium permits using mesh less than 3 inches (7.62 cm), and a trip limit of 600 lb (0.27 mt) for

vessels issued squid/butterfish incidental catch permits. Once butterfish harvest reaches the trip hold reduction threshold to move from phase 1 to phase 2, the trip limit for longfin squid/butterfish moratorium permit holders will be reduced while in phase 2 to 5,000 lb (2.27 mt) for vessels using greater than or equal to 3-inch (7.62-cm) mesh and 2,500 lb (1.13 mt) for vessels using under 3-inch (7.62-cm) mesh. When butterfish harvest is projected to reach the trip hold reduction thresholds to move from phase 2 to phase 3, the trip limit for all longfin squid/butterfish moratorium permit holders will be reduced while in phase 3 to 500 lb (0.23 mt) to avoid quota overages. For phases 2 and 3, the quota thresholds to reduce the trip limits will vary bimonthly throughout the year, as shown in Tables 4 and 5.

TABLE 3—THREE-PHASE BUTTERFISH MANAGEMENT SYSTEM

Phase	Longfin squid/butterfish moratorium permit trip limit		Squid/butterfish incidental catch permit trip limit
	≥3 inch (7.62 cm) mesh	<3 inch (7.62 cm) mesh	
1	Unlimited	2,500 lb (1.13 mt)	600 lb (0.27 mt).
2	5,000 lb (2.27 mt)	2,500 lb (1.13 mt)	600 lb (0.27 mt).
3	500 lb (0.23 mt)	500 lb (0.23 mt)	600 lb (0.27 mt).

TABLE 4—2013 BUTTERFISH THRESHOLDS FOR REDUCING TRIP LIMITS FROM PHASE 1 TO PHASE 2

Months	Trip limit reduction threshold (percent)	Butterfish harvest (metric tons)
Jan–Feb	40	1,028
Mar–Apr	47	1,208
May–Jun	55	1,414
Jul–Aug	63	1,619
Sept–Oct	71	1,825
Nov–Dec	78	2,005

TABLE 5—2013 BUTTERFISH THRESHOLDS FOR REDUCING TRIP LIMITS FROM PHASE 2 TO PHASE 3

Months	Trip limit reduction threshold (percent)	Butterfish harvest (metric tons)
Jan–Feb	58	1,491
Mar–Apr	64	1,645
May–Jun	71	1,825
Jul–Aug	78	2,005
Sept–Oct	85	2,185
Nov–Dec	91	2,339

Finally, during phase 3, the NMFS Regional Administrator has the authority to adjust the phase 3 trip limit for limited access vessels within the range from 250 (0.11 mt) to 750 lb (0.34 mt) so that butterfish harvest does not exceed the annual DAH.

Final Management Measures for Longfin Squid

The Council also recommended regulatory changes for the longfin squid fishery. Currently, vessels that intend to land greater than 2,500 lb (1.13 mt) of longfin squid are required to notify the Northeast Fisheries Observer Program (NEFOP) at least 72 hr in advance of the start of a trip. Longfin squid vessel owners have reported that the 72-hr call in notification is burdensome, as trips are often planned based on weather, sea conditions, and longfin squid movement patterns, which can be highly variable. Therefore, the Council recommended, and NMFS is changing the longfin pre-trip observer notification requirement from 72 to 48 hr. In addition, to avoid closing the directed longfin fishery close to the end of a trimester, the closure threshold for the directed longfin squid fishery will change on April 15 (2 weeks prior to the end of Trimester 1) and August 15 (2 weeks prior to the end of Trimester 2) of each year from 90 to 95 percent.

Final Management Measures for the Butterfish Mortality Cap in the Longfin Squid Fishery

To avoid closing the directed longfin squid fishery due to the butterfish mortality cap in the last 2 weeks of Trimester 1, NMFS is changing the closure threshold on April 15 of each year from 80 to 90 percent. In addition, NMFS will close the directed longfin squid fishery in Trimester 2 if 75 percent of the annual mortality cap is projected to be reached. As there is currently no closure mechanism for the butterfish mortality cap in Trimester 2, the entire annual butterfish mortality cap could potentially be harvested in Trimester 2, which would not leave any butterfish mortality cap quota for the Trimester 3 longfin squid fishery. This change is being implemented to avoid the entire allocation of the butterfish mortality cap being harvested prior to the start of Trimester 3 on September 1 of each fishing year.

This final rule also contains minor corrections to existing regulations. The corrections do not change the intent of any regulations; they only clarify the existing regulations by correcting minor errors. The current accountability measure regulations at § 648.24 state that NMFS will implement any changes to the ACL due to overages from the previous year through notification in the **Federal Register**, by March 31 of the fishing year in which the deductions will be made. However, due to delayed reporting and analysis time to estimate discards in the MSB fisheries, finalized data are not available until April 15 of each year. Therefore, NMFS will publish a notification in the **Federal Register** announcing any overage deductions by May 15 of the fishing year in which the deductions will be made.

This rule also corrects § 648.22(b)(2) regarding the mackerel ABC. This rule clarifies that the MAFMC's SSC recommends a stock-wide ABC, and that the Domestic ABC or ACL is calculated by deducting Canadian catch from the stock-wide ABC. This rule also corrects § 648.27(c) to clarify that the pre-trip notification requirement for vessels issued longfin squid/butterfish moratorium permits is for trips with landings greater than 2,500 lb (1.13 mt). While vessels previously issued longfin squid/butterfish moratorium permits intending to land greater than or equal to 2,500 lb (1.13 mt) were required to call into the pre-trip notification system, this action clarifies that only such vessels intending to land greater than 2,500 lb (1.13 mt) (ex. 2,501 mt) are required to call into the pre-trip notification system. Only those trips with longfin squid landings of 2,501 lb (1.13 mt) and greater will be used to estimate the butterfish mortality cap.

This rule also responds to comments on the 2012 Revised Butterfish Specifications, which were published in an interim final rule on November 9, 2012 (77 FR 67305). The 2013 butterfish specifications implemented in this rule supersede the 2012 Revised Butterfish Specifications implemented in that interim final rule. Therefore, instead of publishing a final rule to address comments received on the interim final

rule, such comments are addressed in this final rule.

Comments and Responses on the 2013 MSB Specifications

NMFS received six comments on the 2013 MSB specifications from: One member of the public; one on behalf of Deep Sea Fish of Rhode Island, Inc. (a freezer/processor in Rhode Island); one on behalf of Seafreeze, Ltd. (a frozen seafood producer based in Rhode Island); one from the Garden State Seafood Association (GSSA) (an industry group representing members of the commercial fishing industry in New Jersey); one from Lund's Fisheries, Inc. (a seafood processing facility in New Jersey), and one from Tokai International, Inc. (an export business that ships seafood to Japan).

Comment 1: Deep Sea Fish of Rhode Island, Inc., Tokai International Inc., and SeaFreeze, Ltd., commented in support of increasing the 2013 butterfish specifications and are in favor of implementing the 2013 MSB specifications on or before January 1, 2013, so that the butterfish fishing industry can take advantage of the early winter Japanese export market when butterfish have the highest fat content. Tokai International, Inc., noted that the fat content of butterfish begins to decrease in February, making butterfish less marketable.

Response: NMFS has published this final rule as soon as possible so that the butterfish fishing industry can take advantage of the increase in quota for the directed fishery. We recognize that the increase in the directed butterfish fishery quota would be less valuable to the butterfish industry if delayed further into the fishing year. Due to concerns about the lost economic opportunity from delaying the effectiveness of this rule for 30 days to comply with the Administrative Procedure Act, there exists good cause to waive the 30-day effectiveness period and implements the 2013 MSB specifications on the date of publication in the **Federal Register**.

Comment 2: GSSA and Lund's Fisheries, Inc., commented in support of the increased butterfish specifications, the proposed management measures for butterfish and longfin squid, the butterfish mortality cap in the longfin squid fishery, and corrections to the MSB regulations.

Response: NMFS is implementing the proposed butterfish specifications, management measures for butterfish and longfin squid, the butterfish mortality cap, and the corrections to the MSB regulations in this final rule.

Comment 3: GSSA and Lund's Fisheries, Inc., commented in support of the 2013–2015 Atlantic mackerel specifications, but noted some changes to the mackerel specification setting process that should be considered for the future, such as modifying the method to account for Canadian catch, accounting for discards in the recreational fishery allocation, and reconsidering the buffer for management uncertainty in setting the commercial ACT. GSSA and Lund's expressed disappointment that the process of setting the U.S. ABC does not provide a mechanism to increase the U.S. ABC if Canadian catches are smaller than predicted. Lund's suggested that Canadian underages should be added to the U.S. ABC in an in-season adjustment. GSSA and Lund's also commented that a discard rate should have been applied to the recreational allocation.

Response: The addition of a mechanism to increase the U.S. ABC if Canadian catches are smaller than predicted would represent a significant change to the commercial quota system for mackerel. Such an adjustment would need to be considered through the Council process, and could only be implemented through a framework adjustment or an amendment to the FMP, rather than through specifications. The Council would, therefore, have to consider such a mechanism in a future action. In addition, reliable discard estimates for the recreational fishery are not available. Given the past performance of the recreational fishery, and the 10-percent buffer, NMFS believes that the potential for discards was adequately accounted for. The Marine Recreational Information Program (MRIP) estimates three types of recreational catch: Fish brought back to the dock in a form that can be identified by trained interviewers; fish that are used for bait, released dead, or filleted and are identified by individual anglers; and fish that are released alive and are identified by individual anglers. The MRIP estimate of recreational catch in 2011, the most recent year of complete data, was 932 mt. As the MRIP data do include some limited information on recreational discards, the mackerel recreational allocation for 2013–2015 of 2,443 mt is likely sufficient to cover both recreational catch and discards. As NMFS improves recreational data collection, the MSB Monitoring Committee will re-examine the recreational ACT and consider whether discards should be accounted for in an explicit deduction.

Comment 4: GSSA and Lund's also commented that the commercial ACT should have been set equal to the commercial ACL, with zero buffer for management uncertainty (instead of the 15-percent buffer proposed for 2013–2015) considering the mackerel fishery's performance is consistent with the specifications that have been set for the fishery in recent years.

Response: Given recent performance of the fishery, NMFS, consistent with the Council's recommendation, determined that a 15-percent buffer between the commercial ACL and ACT was appropriate to prevent overages of the U.S. ABC, and to provide buffer for uncertainty in Canadian catch estimates. While preliminary information provided to the Council during its decision-making process showed Canadian catch in 2013 may be set at lower levels than 2012, it is unclear whether the decrease in Canadian catch is due to concerns about the status of the mackerel stock or other unknown factors. Therefore, NMFS concurs with the Council that setting Canadian catch and the buffer for management uncertainty at status quo levels (15 percent between the commercial ACL and ACT) is appropriate, due to the general uncertainty associated with the mackerel stock and the final Canadian assessment results. In addition, the buffer for management uncertainty includes consideration of management uncertainty issues for commercial catch estimation, including discard estimation and general imprecision in catch estimation.

Comment 5: A member of the public commented that the butterfish quotas should not be increased, but should be decreased by 75 percent instead.

Response: NMFS does not believe that there is any information to warrant a decrease in the butterfish specifications for 2013. On the contrary, the NEFSC analysis showed that the increasing the butterfish catch to 16,800 mt would not lead to overfishing.

Comments on Revised 2012 Butterfish Specifications

NMFS recently published an interim final rule to revise 2012 butterfish specifications (77 FR 67305; November 9, 2012). The interim final rule raised the 2012 butterfish ABC to 4,200 mt (from 3,622 mt), and specified the butterfish ACT at 3,780 mt, the DAH DAP at 872 mt, and the butterfish mortality cap at 3,165 mt. The rationale for the interim final rule is discussed in the background section of the preamble for that action and is not repeated here.

The rule specified that these revised butterfish quotas would be effective from November 8, 2012, through the remainder of the 2012 fishing year (December 31, 2012), until superseded by 2013 MSB specifications. Typically

NMFS would publish a rulemaking to finalize the measures put forward in an interim final rule, and use the final rule to respond to any comments on the interim final measures. Because of the timing of a rulemaking to finalize the revised 2012 butterfish specifications and the timing of this final rule to implement 2013 MSB specifications coincide, and because the 2013 MSB specifications would supersede the 2012 measures, NMFS decided to forego the publication of a rulemaking to finalize the revised 2012 butterfish specifications and to instead respond to comments on the revised 2012 butterfish specification in the final rule for 2013 MSB specifications. One individual submitted a comment on the interim final rule, and NMFS addresses the comment below, in two parts.

Comment 1: One individual commented that NMFS raised the ABC on a stock for which the overfished/overfishing status is unknown. The commenter stated that while NMFS previously classified butterfish as overfished with overfishing occurring, the SSC was forced by NMFS to change the determination so that the longfin squid fishery could continue to operate. The commenter stated that the butterfish stock is so depleted that the directed fishery has not attained its quota for the 2012 fishing year. The commenter also stated that the fishery did not catch the directed fishery quota in previous years because bycatch closures closed the directed fishery before the fish were available to fishery participants from southern states that rely on butterfish catch in the fall. Finally, the commenter stated that the longfin squid fishery is wasteful, and is characterized by the excessive catch of undersized fish due to the small mesh size used to prosecute the fishery.

Response: The commenter incorrectly characterizes the current and previous status of the butterfish stock. Until recently, NMFS listed butterfish as overfished (i.e., stock biomass below the overfishing threshold), with overfishing not occurring (i.e., fishing mortality was not occurring at a rate higher than the stock's natural replenishment rate) based on the results of the 38th Stock Assessment Review Workshop (SAW 38; 2004). NMFS, rather than the Council's SSC, officially changed the overfished status for butterfish to ''unknown'' in mid-2012, after a review of the results of the 49th Stock Assessment Review Workshop (SAW 49; 2010) suggested that the stock status reference points that resulted from SAW 38 (i.e. the overfished status from SAW 38) were inappropriate. The overfishing status for butterfish has not been changed. The change to the stock status determination was entirely separate from any 2012 rulemakings related to either the longfin squid or butterfish fisheries. NMFS did not change the butterfish overfished status from ''overfished'' to ''unknown'' to facilitate a longfin squid fishery during the 2012 fishing year.

The commenter does not present support for the statement that butterfish stock depletion has caused the fishery to catch less than the 2012 butterfish quota. To the contrary, recent trawl survey indices indicate that butterfish abundance is stable or increasing. In addition, management controls in recent years have constrained landings. While NMFS has increased the butterfish quota at several points during the 2012 fishing year, possession limits restrict the amount of butterfish that limited access and incidental butterfish permit holders can land on a given trip (up to 5,000 lb per trip for limited access permit holders, depending on mesh size, and up to 650 per trip for incidental permit holders). Further, the directed butterfish fishery quota (DAH) has been maintained at a low level since 2004 in order to limit fishing mortality on the butterfish stock following the ''overfished'' status determination in SAW 38. The previous low DAH, coupled with possession limits, has prevented the formation of a strong market for butterfish, and more likely explains why the DAH has not been attained in 2012 in spite of quota increases.

Comment 2: The commenter also stated that the directed fishery quota was not attained in previous years because ''bycatch closures'' closed the directed fishery before the fish were available to southern fishery participants in the fall.

Response: This comment is unclear. If the commenter is referring to closures of the directed butterfish fishery (based on the DAH) in recent years, these closures were the result of directed butterfish landings, not a result of bycatch limits due to butterfish bycatch in other fisheries. If the commenter is referring to the availability of butterfish mortality cap quota for fall participants in the longfin squid fishery, NMFS notes that the butterfish mortality cap was not constraining for fall participants in the longfin squid fishery in either 2011 or 2012, the only 2 years that the cap has been in operation. The Trimester III (September 1–December 31) longfin squid fishery operated without a closure related to butterfish for both years.

Finally, regarding incidental catch in the longfin squid fishery, NMFS notes that fishery management plans for managed species consider incidental catch and discards. This means that annual catch levels are set so that mortality from all sources, including incidental catch and discards in the longfin squid fishery, are accounted for. Thus, while there is incidental catch of other species in the longfin squid fishery, NMFS works to constrain such catch within the context of overall catch levels appropriate for each managed stock.

Changes From the Proposed Rule

There are no changes from the proposed rule to the mackerel or butterfish specifications or management measures.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the MSB FMP, other provision of the Magnuson-Stevens Act, and other applicable laws.

The Council prepared an EA for the 2013 specifications, and the NOAA Assistant Administrator for Fisheries concluded that there will be no significant impact on the human environment as a result of this rule. A copy of the EA is available upon request (see **ADDRESSES**).

This action is authorized by 50 CFR part 648 and has been determined to be not significant for purposes of Executive Order 12866 (E.O. 12866).

The Assistant Administrator for Fisheries finds good cause under section 553(d) of the Administrative Procedure Act to waive the 30-day delay in effectiveness for this action for all requirements except for those in 648.27. This action increases the butterfish harvest available to the fishing industry for the 2013 fishing year. The primary butterfish market available to the butterfish fishing industry occurs in late December through mid-February due to the high fat content of the fish after feeding during the early winter. In addition, the current regulations cap the butterfish trip limit at 5,000 lb (2,268 kg) for limited access permit holders, while this final rule implements an unlimited trip limit at the start of the fishing year. This change in the trip limit for the directed butterfish fishery will also allow the butterfish fleet to obtain as much profit early in the year as possible, when the market is available. If the effectiveness of this rule were delayed for 30 days from the date of publication, it would likely be effective after the butterfish market has decreased. Therefore, vessels fishing for butterfish would be unable to obtain the

increased economic opportunity this final rule provides by increasing the butterfish quota. Failure to make this final rule effective immediately will undermine the intent of the rule, which is to promote the utilization and conservation of the Atlantic mackerel, squid, and butterfish resource.

NMFS, pursuant to section 604 of the Regulatory Flexibility Act, has prepared a FRFA, included in the preamble of this final rule, in support of the 2013 specifications and management measures. The FRFA describes the economic impact that this final rule, along with other non-preferred alternatives, will have on small entities.

The FRFA incorporates the economic impacts and analysis summaries in the IRFA, a summary of the significant issues raised by the public in response to the IRFA, and NMFS's responses to those comments. A copy of the IRFA, the RIR, and the EA are available upon request (see **ADDRESSES**).

Statement of Need for This Action

This action proposes 2013–2015 specifications for mackerel and 2013 specifications for butterfish, along with management measures for longfin squid and butterfish. A complete description of the reasons why this action is being considered, and the objectives of and legal basis for this action, are contained in the preamble to the proposed and final rules and are not repeated here.

A Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

There were no issues related to the IRFA or the economic impacts of the rule more generally raised in public comments.

Description and Estimate of Number of Small Entities to Which the Rule Will Apply

Based on permit data for 2011, 3,405 commercial or charter vessels possessed MSB permits for the 2011 fishing year, and similar numbers of vessels are expected to have MSB permits for 2013. All but a few of these participants can be considered small businesses under the guidelines of the Small Business Administration (SBA). Small businesses operating in commercial and recreational (i.e., party and charter vessel operations) fisheries have been defined by the SBA as firms with gross revenues of up to $4.0 and $7.0 million, respectively. There are no large entities, as that term is defined in section 601 of the RFA, participating in this fishery. Therefore, there are no disproportionate economic impacts on small entities. Many vessels participate in more than one of these fisheries; therefore, permit numbers are not additive.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action. In addition, there are no Federal rules that duplicate, overlap, or conflict with this rule.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impacts on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

Actions Implemented With the Final Rule

The mackerel commercial DAH (33,821 mt) and recreational ACT/RHL (2,443 mt) implemented in this action represent no change from status quo. Commercial mackerel landings for 2011 were 1,463 mt, and recreational catch was 932 mt, and in both cases, catch was below the allocation. As of the publication of this rule, mackerel catch is estimated to be 5,325 mt and is not likely to increase significantly for the remainder of the year, which means that 2012 catch will also be below the 2012 DAH. Therefore, this action allows the mackerel fleet the opportunity to harvest more than they have in the previous year. Overall, this action is expected to generate revenue very similar to the 2012 revenue for vessels that participate in the commercial mackerel fisheries.

The butterfish DAH implemented in this action (2,570 mt) represents an increase of 1,698 mt over the 2012 DAH (872 mt). Due to market conditions, there has not been a directed butterfish fishery since 2001; therefore, recent landings have been low. The increase in the DAH has the potential to dramatically increase revenue for butterfish permitted vessels because the butterfish fishery has been an incidental catch fishery for several years.

In addition, the three-phased management system implemented for the directed butterfish fishery, which allows an unlimited quota until butterfish harvest reaches a particular threshold, allows vessels to harvest substantially more butterfish during the start of the fishing year, when the market is suspected to be available. The three-phased management system allows the potentially expanded directed butterfish fishery to increase catch without exceeding the ACL and having to pay back overages the following year.

The butterfish mortality cap implemented in this action (4,464 mt) represents a 1,299-mt increase over the current 2012 cap level (3,165 mt). The increase in the butterfish mortality cap is less restrictive on the longfin squid fishery than the previous year. While longfin squid catch will still be restrained by the longfin squid DAH, there is less of likelihood that the longfin squid fishery will be closed due to the butterfish mortality cap. In addition, the management measures for the longfin squid fishery that are being implemented will ensure that the directed longfin squid fishery is not closed during the last 2 weeks of a particular Trimester, therefore causing economic harm to the fishing industry when there is still a small amount of catch available to the fleet. Therefore, the implementation of these actions could result in an increase in revenue for the longfin squid fishery for 2013.

The *Illex* and longfin squid IOYs confirmed in this action (22,915 mt and 22,049 mt respectively) represent no change from the status quo. Thus, implementation of this action should not result in a reduction in revenue or a constraint on expansion of the fishery in 2013.

Alternatives to Actions in the Final Rule

The Council analysis evaluated three alternatives to the specifications for mackerel. The first (status quo) alternative differed from the mackerel specifications implemented, only in that the status quo alternative recommends specifications for 1 year, while the final specifications are being implemented for 3 years (2013–2015). The status quo alternative would have set the stock-wide ABC of 80,000 mt, Canadian catch of 36,219 mt, and a U.S. ABC of 43,781 mt. The second alternative (the least restrictive) would have set the stock-wide ABC at 100,000 mt, maintained Canadian catch at 35,219 mt, and would have set a U.S. ABC at 63,781 mt. This alternative could have generated increased revenue if more mackerel became available to the fishery. The third alternative (the most restrictive) would have set the stock-wide ABC at

60,000 mt, maintain Canadian catch at 36,219 mt, and would have set a U.S. ABC at 23,781 mt. This alternative could have generated the lowest revenue of all of the alternatives. These two alternatives were not selected because they were inconsistent with the ABC recommended by the SSC.

There were three alternatives to the butterfish specifications being implemented that were not selected by the Council. The first (status quo) alternative would have kept the butterfish ABC and ACL at 3,622 mt, the ACT at 3,260 mt, the DAH and DAP at 1,087, and the butterfish mortality cap at 2,445 mt. The second alternative (least restrictive) would have set the ABC and ACL at 10,500 mt, the ACT at 9,450 mt, the DAH and DAP at 3,213 mt, and the butterfish mortality cap at 5,625 mt, and would have generated the highest revenues of all of the alternatives. The fourth alternative (most restrictive) would have set the ABC and ACL at 6,300 mt, the ACT at 5,670 mt, the DAH and DAP at 1,928 mt, the butterfish mortality cap at 3,375 mt, and would have generated the lowest revenue of all of the alternatives. These three alternatives were not selected because they were inconsistent with the ABC recommended by the SSC.

The Council recommended the status quo as an alternative to changing management measures for the longfin squid fishery and for the butterfish mortality cap. The status quo alternative would have required vessels possessing 1,000 lb (0.45 mt) or more of butterfish to fish with a 3-inch (76-mm) minimum codend mesh. The status quo alternatives were considered, but not selected, because the measures implemented have the potential to increase economic opportunity for the fishing fleet while still ensuring the ACL for the longfin squid fishery and the butterfish mortality cap are not exceeded. There were also two alternatives to the proposed three-phase management system for the directed butterfish fishery. The first (status quo and most restrictive) would have maintained the 5,000-lb (2.27-mt) trip limit for vessels issued longfin squid/butterfish moratorium permits using over 3-inch (76-mm) mesh, 2,000-lb (0.91-mt) trip limit for vessels issued longfin squid/butterfish moratorium permits using under 3-inch (76-mm) mesh, and the 600-lb (0.27-mt) trip limit for vessels issued squid/butterfish incidental catch permits. Even with the increase in quota, the butterfish fishery may not have been able to harvest an increased amount of butterfish with these restrictive trip limits. Therefore, this alternative would have generated the lowest amount of revenue out of all of the alternatives. The second alternative would have provided a simpler management system for the directed fishery in which the trip limit for vessels issued longfin squid/butterfish moratorium permits would have been 20,000 lb (9.07 mt) for vessels issued longfin squid/butterfish moratorium permits using greater than 3-inch (76-mm) mesh, 2,500 lb (1.13 mt) for vessels using under 3-inch (76-mm) mesh, and 1,000 lb (4.54 mt) for vessels issued squid/butterfish incidental catch permits. If 80 percent of the DAH was projected to be harvested before October 1, the trip limit for all vessels would have been reduced to 250 lb (0.11 mt), and if the DAH was projected to be harvested on or after October 1, the trip limit for all vessels would have been 500 lb (0.23 mt). This alternative would have provided the butterfish fishery the opportunity to increase revenues over the first alternative, but not to the same extent as the alternative implemented in this action. While these alternatives were considered, they were not selected because the alternative being implemented has the potential to increase economic opportunity for vessels participating in the directed butterfish fishery while still ensuring the ACL is not exceeded. The other alternatives would not have been as effective for directed butterfish vessels to re-establish a butterfish market.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: January 10, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.4, paragraph (a)(5)(ii) is revised to read as follows:

§ 648.4 Vessel permits.

* * * * *

(a) * * *

(5) * * *

(ii) *Squid/butterfish incidental catch permit.* Any vessel of the United States may obtain a permit to fish for or retain up to 2,500 lb (1.13 mt) of longfin squid, 600 lb (0.27 mt) of butterfish, or up to 10,000 lb (4.54 mt) of *Illex* squid, as an incidental catch in another directed fishery. The incidental catch allowance may be revised by the Regional Administrator based upon a recommendation by the Council following the procedure set forth in § 648.22.

* * * * *

■ 3. In § 648.14, paragraphs (g)(2)(ii)(E) and (F) are revised to read as follows:

§ 648.14 Prohibitions.

* * * * *

(g) * * *

(2) * * *

(ii) * * *

(E) Possess more than 2,500 lb (1.13 mt) of butterfish, unless the vessel meets the minimum mesh requirements specified in § 648.23(a).

(F) Take, retain, possess, or land mackerel after a total closure specified under § 648.24(b)(1).

* * * * *

■ 4. In § 648.22, revise paragraphs (b)(2)(i) and (b)(2)(ii), redesignate paragraphs (b)(3)(v) through (b)(3)(vii) as paragraphs (b)(3)(vi) through (b)(3)(viii), respectively, and add new paragraph (b)(3)(v) to read as follows:

§ 648.22 Atlantic mackerel, squid, and butterfish specifications.

* * * * *

(b) * * *

(2) Mackerel—(i) *ABC.* The MAFMC's SSC shall recommend a stock-wide ABC to the MAFMC, as described in § 648.20. The stock-wide mackerel ABC is reduced from the OFL based on an adjustment for scientific uncertainty; the stock-wide ABC must be less than or equal to the OFL.

(ii) *ACL.* The ACL or Domestic ABC is calculated using the formula ACL/Domestic ABC = stock-wide ABC − C, where C is the estimated catch of mackerel in Canadian waters for the upcoming fishing year.

* * * * *

(3) * * *

(v) The trip limit reduction thresholds for phase 2 and phase 3 of the butterfish three-phase management system will be modified annually through the specifications process. Trip limit reduction thresholds vary bi-monthly and are set to allow the butterfish fishery to continue to operate without exceeding the stock-wide ACL. An example of the phase 2 and 3 trip limit reduction thresholds is shown in the table below:

BUTTERFISH THRESHOLDS FOR REDUCING TRIP LIMITS FROM PHASE 1 TO PHASE 2

Months	Trip limit reduction threshold (percent)	Butterfish harvest (metric tons)
Jan–Feb	40	1,028
Mar–Apr	47	1,208
May–Jun ...	55	1,414
Jul–Aug	63	1,619
Sept–Oct ...	71	1,825
Nov–ec	78	2,005

* * * * *

■ 5. In § 648.23, paragraph (a)(1) is revised to read as follows:

§ 648.23 Mackerel, squid, and butterfish gear restrictions.

(a) * * *

(1) *Butterfish fishery.* Owners or operators of otter trawl vessels possessing 2,500 lb (1.13 mt) or more of butterfish harvested in or from the EEZ may only fish with nets having a minimum codend mesh of 3 inches (7.62 cm) diamond mesh, inside stretch measure, applied throughout the codend for at least 100 continuous meshes forward of the terminus of the net, or for codends with less than 100 meshes, the minimum mesh size codend shall be a minimum of one-third of the net, measured from the terminus of the codend to the headrope.

* * * * *

■ 6. In § 648.24, paragraphs (a)(1), (b)(6), (c) and (d) are revised to read as follows:

§ 648.24 Fishery closures and accountability measures.

(a) *Fishery closure procedures*—(1) *Longfin squid.* NMFS shall close the directed fishery in the EEZ for longfin squid when the Regional Administrator projects that 90 percent of the longfin squid quota is harvested before April 15 of Trimester I and/or August 15 of Trimester II, and when 95 percent of the longfin squid DAH has been harvested in Trimester III. On or after April 15 of Trimester I and/or August 15 of Trimester II, NMFS shall close the directed fishery in the EEZ for longfin squid when the Regional Administrator projects that 95 percent of the longfin squid quota is harvested. The closure of the directed fishery shall be in effect for the remainder of that fishing period, with incidental catches allowed as specified at § 648.26.

* * * * *

(b) * * *

(6) *Mackerel ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (landings and discards). Both landings and dead discards will be evaluated in determining if the ACL has been exceeded. NMFS shall make determinations about overages and implement any changes to the ACL, in accordance with the Administrative Procedure Act, through notification in the **Federal Register**, by May 15 of the fishing year in which the deductions will be made.

(c) *Butterfish AMs*—(1) *Butterfish three-phase management system.* The butterfish fishery operates under a three-phase management system. Phase 1 begins annually at the start of the fishing year on January 1. Trip limit reductions are implemented in phase 2 and 3 dependent upon the amount of butterfish harvest and the trip limit reduction thresholds set during the specification process as described in § 648.22.

(i) *Phase 1.* During phase 1, vessels issued a longfin squid/butterfish moratorium permit (as specified at § 648.4(a)(5)(i)) fishing with a minimum mesh size of 3 inches (76 mm) have an unlimited trip limit and vessels issued a longfin squid/butterfish moratorium permit fishing with mesh less than 3 inches (76 mm) are prohibited from landing more than 2,500 lb (1.13 mt) of butterfish per trip.

(ii) *Phase 2.* NMFS shall reduce the trip limit for vessels issued longfin squid/butterfish moratorium permits (as specified at § 648.4(a)(5)(i)) fishing with a minimum mesh size of 3 inches (76 mm) to 5,000 lb (2.27 mt), when butterfish harvest reaches the relevant phase 2 trip limit reduction threshold. Trip limits for vessels issued longfin squid/butterfish moratorium permits fishing with mesh less than 3 inches (76 mm) will remain at 2,500 lb (1.13 mt) of butterfish per trip.

(iii) *Phase 3.* NMFS shall subsequently reduce the trip limit for vessels issued longfin squid/butterfish moratorium permits to 500 lb (0.23 mt), regardless of minimum mesh size, when butterfish harvest is projected to reach the relevant phase 3 trip limit reduction threshold. The NMFS Regional Administrator may adjust the butterfish trip limit during phase 3 of the directed butterfish fishery anywhere from 250 lb (0.11 mt) to 750 lb (0.34 mt) to ensure butterfish harvest does not exceed the specified DAH.

(2) *Butterfish ACL overage repayment.* If the butterfish ACL is exceeded, then catch in excess of the ACL will be deducted from the ACL the following year, as a single-year adjustment.

(3) *Butterfish mortality cap on the longfin squid fishery.* NMFS shall close the directed fishery in the EEZ for longfin squid when the Regional Administrator projects that 80 percent of the Trimester I butterfish mortality cap allocation has been harvested in Trimester I, when 75 percent of the annual butterfish mortality cap has been harvested in Trimester II, and/or when 90 percent of the butterfish mortality cap has been harvested in Trimester III.

(4) *Butterfish ACL overage evaluation.* The ACL will be evaluated based on a single-year examination of total catch (landings and discards). Both landings and dead discards will be evaluated in determining if the ACL has been exceeded. NMFS shall make determinations about overages and implement any changes to the ACL, in accordance with the Administrative Procedure Act, through notification in the **Federal Register**, by May 15 of the fishing year in which the deductions will be made.

(d) *Notification.* Upon determining that a closure or trip limit reduction is necessary, the Regional Administrator will notify, in advance of the closure, the Executive Directors of the MAFMC, NEFMC, and SAFMC; mail notification of the closure or trip limit reduction to all holders of mackerel, squid, and butterfish fishery permits at least 72 hr before the effective date of the closure; provide adequate notice of the closure or trip limit reduction to recreational participants in the fishery; and publish notification of the closure or trip limit reduction in the **Federal Register**.

■ 7. In § 648.26, paragraph (d) is revised to read as follows:

§ 648.26 Mackerel, squid, and butterfish possession restrictions.

* * * * *

(d) *Butterfish.* (1) *Phase 1.* A vessel issued a longfin squid/butterfish moratorium permit (as specified at § 648.4(a)(5)(i)) fishing with a minimum mesh size of 3 inches (76 mm) is authorized to fish for, possess, or land butterfish with no possession restriction in the EEZ per trip, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours, provided that butterfish harvest has not reached the phase 2 trip limit reduction threshold, as described in § 648.24(c). Vessels issued longfin squid/butterfish moratorium permits fishing with mesh less than 3 inches (76 mm) may not fish for, possess, or land more than 2,500 lb (1.13 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, provided that butterfish harvest has not reached the phase 3 trip limit reduction threshold, as described in § 648.24(c).

(2) *Phase 2.* When butterfish harvest reaches the phase 2 trip limit reduction threshold for the butterfish fishery (as described in § 648.24), vessels issued a longfin squid/butterfish moratorium permit (as specified at § 648.4(a)(5)(i)) fishing with a minimum mesh size of 3 inches (76 mm) may not fish for, possess, or land more than 5,000 lb (2.27 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. Trip limits for vessels issued butterfish moratorium permits fishing with mesh less than 3 inches (76 mm) will remain at 2,500 lb (1.13) per trip.

(3) *Phase 3.* When butterfish harvest is projected to reach the trip limit reduction threshold for phase 3 (as described in § 648.24), all vessels issued a longfin squid/butterfish moratorium permit, regardless of mesh size used, may not fish for, possess, or land more than 500 lb (0.23 mt) of butterfish per trip at any time, and may only land butterfish once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours. If a vessel has been issued a longfin squid/butterfish incidental catch permit (as specified at § 648.4(a)(5)(ii)), it may not fish for, possess, or land more than 600 lb (0.27 mt) of butterfish per trip at any time.

■ 8. In § 648.27, paragraphs (a), (c), and (d) are revised to read as follows:

§ 648.27 Observer requirements for the longfin squid fishery.

(a) A vessel issued a longfin squid and butterfish moratorium permit, as specified at § 648.4(a)(5)(i), must, for the purposes of observer deployment, have a representative provide notice to NMFS of the vessel name, vessel permit number, contact name for coordination of observer deployment, telephone number or email address for contact; and the date, time, port of departure, and approximate trip duration, at least 48 hr, but no more than 10 days, prior to beginning any fishing trip, unless it complies with the possession restrictions in paragraph (c) of this section.

* * * * *

(c) A vessel issued a longfin squid and butterfish moratorium permit, as specified in § 648.4(a)(5)(i), that does not have a representative provide the trip notification required in paragraph (a) of this section is prohibited from fishing for, possessing, harvesting, or landing greater than 2,500 lb (1.13 mt) of longfin squid per trip at any time, and may only land longfin squid once on any calendar day, which is defined as the 24-hr period beginning at 0001 hours and ending at 2400 hours.

(d) If a vessel issued a longfin squid and butterfish moratorium permit, as specified in § 648.4(a)(5)(i), intends to possess, harvest, or land more than 2,500 lb (1.13 mt) of longfin squid per trip or per calendar day, has a representative notify NMFS of an upcoming trip, is selected by NMFS to carry an observer, and then cancels that trip, the representative is required to provide notice to NMFS of the vessel name, vessel permit number, contact name for coordination of observer deployment, and telephone number or email address for contact, and the intended date, time, and port of departure for the cancelled trip prior to the planned departure time. In addition, if a trip selected for observer coverage is cancelled, then that vessel is required to carry an observer, provided an observer is available, on its next trip.

[FR Doc. 2013–00827 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 78, No. 11

Wednesday, January 16, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0023; Directorate Identifier 96–CE–072–AD]

RIN 2120–AA64

Airworthiness Directives; Various Aircraft Equipped With Wing Lift Struts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to revise an existing airworthiness directive (AD) that applies to certain aircraft equipped with wing lift struts. The existing AD currently requires repetitively inspecting the wing lift struts for corrosion; repetitively inspecting the wing lift strut forks for cracks; replacing any corroded wing lift strut; replacing any cracked wing lift strut fork; and repetitively replacing the wing lift strut forks at a specified time for certain airplanes. The existing AD also currently requires incorporating a ''NO STEP'' placard on the wing lift strut. Since we issued that AD, we have been informed that paragraph (c) in the existing AD is being misinterpreted and causing confusion. This proposed AD would clarify the intent of the language currently in paragraph (c) of the existing AD and would retain all other requirements of the existing AD. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 4, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; Internet: *www.piper.com.* Copies of the instructions to the F. Atlee Dodge supplemental type certificate (STC) and information about the Jensen Aircraft STCs may be obtained from F. Atlee Dodge, Aircraft Services, LLC., 6672 Wes Way, Anchorage, Alaska 99518–0409, Internet: *www.fadodge.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gregory ''Keith'' Noles, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0023; Directorate Identifier 96–CE–072–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On December 22, 1998, we issued AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998), for all The New Piper Aircraft, Inc. (currently Piper Aircraft, Inc.) airplane models equipped with wing lift struts. That AD superseded AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993), and requires repetitively inspecting the wing lift struts for corrosion; repetitively inspecting the wing lift strut forks for cracks; replacing any corroded and/or dented wing lift strut; replacing any cracked wing lift strut fork; and repetitively replacing the wing lift strut forks at a specified time for certain airplanes. That AD also requires incorporating a ''NO STEP'' placard on the wing lift strut and provides the option of installing certain sealed wing lift struts that include the lift strut forks as terminating action for repetitive inspection and replacement requirements.

AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993), resulted from reports of corrosion damage found on the wing lift struts and cracking found on the wing lift strut forks. AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998), resulted from a need to clarify certain requirements of AD 93–10–06, eliminated the lift strut fork repetitive inspection requirement for the Piper PA–25 series airplanes, incorporated airplane models inadvertently omitted from the applicability, and required installing a placard on the lift strut.

We issued both ADs to detect and correct corrosion and cracking on the front and rear wing lift struts and forks, which could cause the wing lift strut to fail. This failure could result in the wing separating from the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), we have been informed that the language in paragraph (c) is being misinterpreted and causing confusion. Paragraph (c) of the existing AD currently states, ''If holes are drilled in wing lift strut assemblies installed in accordance with (a)(4) or (b)(3) of this AD to attach cuffs, door clips, or other hardware, inspect the wing lift struts at intervals not to exceed 24 calendar months using the procedures specified in either paragraphs (a)(1) or (a)(2), including all subparagraphs, of this AD.''

Our intention was to specify that if a sealed wing lift strut assembly is installed as a replacement part, the repetitive inspection requirement is terminated only if the seal is never broken. We also intended to specify that if the seal is broken then that wing lift strut becomes subject to continued repetitive inspections.

We did not intend to promote drilling holes into or otherwise unsealing a sealed strut, nor did we intend to preclude a proper maintenance action that may temporarily unseal a sealed strut if all appropriate issues are considered, such as static strength, fatigue, material effects, immediate and long-term (internal and external) corrosion protection, resealing methods, etc. Current FAA regulations in 14 CFR 43.13(b) specify that maintenance performed will result in the part's condition to be at least equal to its original or properly altered condition. There are provisions in this proposed AD for approving such actions as an alternative method of compliance (AMOC).

Also, some type certificates held by Piper at the time AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), was issued now belong to other owners. We have modified the applicability to reflect these changes in ownership.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998). This proposed AD would also clarify our intent of required actions if the seal on a sealed wing lift strut is ever broken.

Paragraph Designation Changes to the Existing AD

Since AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

TABLE 1—REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 99–01–05	Corresponding requirement in this proposed AD
paragraph (a)	paragraph (h)
paragraph (a)(1)	paragraph (i)(1)
paragraph (a)(1)(i)	paragraph (i)(1)(i)
paragraph (a)(1)(ii)	paragraph (i)(1)(ii)
paragraph (a)(2)	paragraph (i)(2)
paragraph (a)(2)(i)	paragraph (i)(2)(i)
paragraph (a)(2)(ii)	paragraph (i)(2)(ii)
paragraph (a)(3)	paragraph (j)(1)
paragraph (a)(4)	paragraph (j)(2)
paragraph (a)(5)	paragraph (j)(3)
paragraph (b)	paragraph (k)
paragraph (b)(1)	paragraph (l)
paragraph (b)(1)(i)	paragraph (l)(1)
paragraph (b)(1)(ii)(B) & (b)(1)(iv)	paragraph (l)(2)
paragraph (b)(1)(ii)(C) & (b)(1)(iv)	paragraph (l)(3)
paragraph (b)(1)(ii)(A) & (b)(1)(iv)	paragraph (l)(4)
paragraph (b)(1)(iii), (b)(2), (b)(1)(iv)	paragraph (m)(1)
paragraph (b)(3) thru (b)(3)(ii)	paragraph (m)(2)
paragraph (b)(4) thru (b)(4)(vi)	paragraph (m)(3) thru (m)(3)(vi)
paragraph (b)(5) thru (b)(5)(ii)	paragraph (m)(4)
paragraph (c)	removed
paragraph (d)	paragraph (n)(1)
paragraph (d)(1)	paragraph (n)(2)
paragraph (d)(2)	paragraph (n)(3)

Costs of Compliance

We estimate that this proposed AD affects 22,000 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD. However, the only difference in the costs presented below and the costs associated with AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), is the change in the labor rate from $65 per hour to $85 per hour:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of the wing lift struts and wing lift strut forks.	8 work-hours × $85 per hour = $680 per inspection cycle.	Not applicable	$680 per inspection cycle..	$14,960,000 per inspection cycle.
Installation placard	1 work-hour × $85 = $85	$30	$115	$2,530,000

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost per wing lift strut	Parts cost per wing lift strut	Cost per product per wing lift strut
Replacement of the wing lift strut and/or wing lift strut forks	4 work-hours × $85 per hour = $340	$440	$780

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998), and adding the following new AD:

Various Aircraft: Docket No. FAA–2013–0023; Directorate Identifier 96–CE–072–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by March 4, 2013.

(b) Affected ADs

This AD revises AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), which superseded AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993). AD 99–26–19, amendment 39–11479 (64 FR 72524, December 28, 1999), also relates to the subject of this AD.

(c) Applicability

This AD applies to the following aircraft that are:

(1) equipped with wing lift struts; and

(2) certificated in any category.

Type certificate holder	Aircraft model	Serial numbers
FS 2000 Corp	L–14	All
FS 2001 Corp	J5A (Army L–4F), J5A–80, J5B (Army L–4G), J5C, AE–1, and HE–1.	All.
FS 2002 Corporation	PA–14	14–1 through 14–523.
FS 2003 Corporation	PA–12 and PA–12S	12–1 through 12–4036.
LAVIA ARGENTINA S.A. (LAVIASA)	PA–25, PA–25–235, and PA–25–260	25–1 through 25–8156024.
Piper Aircraft, Inc	TG–8 (Army TG–8, Navy XLNP–1)	All.
Piper Aircraft, Inc	E–2 and F–2	All.
Piper Aircraft, Inc	J3C–40, J3C–50, J3C–50S, (Army L–4, L–4B,L–4H, and L–4J), J3C–65 (Navy NE–1 and NE–2), J3C–65S, J3F–50, J3F–50S, J3F–60, J3F–60S, J3F–65 (Army L–4D), J3F–65S, J3L, J3L–S, J3L–65 (Army L–4C), and J3L–65S.	All.
Piper Aircraft, Inc	J4, J4A, J4A–S, and J4E (Army L–4E)	4–401 through 4–1649.
Piper Aircraft, Inc	PA–11 and PA–11S	11–1 through 11–1678.
Piper Aircraft, Inc	PA–15	15–1 through 15–388.
Piper Aircraft, Inc	PA–16 and PA–16S	16–1 through 16–736.
Piper Aircraft, Inc	PA–17	17–1 through 17–215.
Piper Aircraft, Inc	PA–18, PA–18S, PA–18 ''105'' (Special), PA–18S ''105'' (Special), PA–18A, PA–18 ''125'' (Army L–21A), PA–18S ''125'', PA–18AS ''125'', PA–18 ''135'' (Army L–21B), PA–18A ''135'', PA–18S ''135'', PA–18AS ''135'', PA–18 ''150'', PA–18A ''150'', PA–18S ''150'', PA–18AS ''150'', PA–18A (Restricted), PA–18A ''135'' (Restricted), and PA–18A ''150'' (Restricted).	18–1 through 18–8309025, 18900 through 1809032, and 1809034 through 1809040.
Piper Aircraft, Inc	PA–19 (Army L–18C), and PA–19S	19–1, 19–2, and 19–3.
Piper Aircraft, Inc	PA–20, PA–20S, PA–20 ''115'', PA–20S ''115'', PA–20 ''135'', and PA–20S ''135''.	20–1 through 20–1121.
Piper Aircraft, Inc.	PA–22, PA–22–108, PA–22–135, PA–22S–135, PA–22–150, PA–22S–150, PA–22–160, and PA–22S–160.	22–1 through 22–9848.

Note to paragraph (c) of this AD: There are airplanes commonly known as a ''Clipped Wing Cub'', which modify the airplane primarily by removing approximately 40 inches of the inboard portion of each wing. Such airplanes originally were and still are covered under this AD.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

The subject of this AD was originally prompted by reports of corrosion damage found on the wing lift struts. The AD is being revised because of reports that paragraph (c) in the existing AD is being misinterpreted and causing confusion. This AD clarifies the intent of the language currently in paragraph (c) of AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), which is being removed by this AD. Our intention was to specify that if a sealed wing lift strut assembly is installed as a replacement part, the repetitive inspection requirement is terminated only if the seal remains intact. This AD retains all the actions currently required in AD 99–01–05. There are no new requirements in this AD and it does not add any additional burden to the owners/operators of the affected airplanes. We are issuing this AD to detect and correct corrosion and cracking on the front and rear wing lift struts and forks, which could cause the wing lift strut to fail. This failure could result in the wing separating from the airplane.

(f) Paragraph Designation Changes to Existing AD

Since AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998), was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this AD, as listed in the following table:

TABLE 1 TO PARAGRAPH (f) OF THIS AD—REVISED PARAGRAPH IDENTIFIERS

Requirement in AD 99–01–05	Corresponding requirement in this AD
paragraph (a)	paragraph (h)
paragraph (a)(1)	paragraph (i)(1)
paragraph (a)(1)(i)	paragraph (i)(1)(i)
paragraph (a)(1)(ii)	paragraph (i)(1)(ii)
paragraph (a)(2)	paragraph (i)(2)
paragraph (a)(2)(i)	paragraph (i)(2)(i)
paragraph (a)(2)(ii)	paragraph (i)(2)(ii)
paragraph (a)(3)	paragraph (j)(1)
paragraph (a)(4)	paragraph (j)(2)
paragraph (a)(5)	paragraph (j)(3)
paragraph (b)	paragraph (k)
paragraph (b)(1)	paragraph (l)
paragraph (b)(1)(i)	paragraph (l)(1)
paragraph (b)(1)(ii)(B) & (b)(1)(iv)	paragraph (l)(2)
paragraph (b)(1)(ii)(C) & (b)(1)(iv)	paragraph (l)(3)
paragraph (b)(1)(ii)(A) & (b)(1)(iv)	paragraph (l)(4)
paragraph (b)(1)(iii), (b)(2), (b)(1)(iv)	paragraph (m)(1)
paragraph (b)(3) thru (b)(3)(ii)	paragraph (m)(2)
paragraph (b)(4) thru (b)(4)(vi)	paragraph (m)(3) thru (m)(3)(vi)
paragraph (b)(5) thru (b)(5)(ii)	paragraph (m)(4)
Paragraph (c)	Removed
paragraph (d)	paragraph (n)(1)
paragraph (d)(1)	paragraph (n)(2)
paragraph (d)(2)	paragraph (n)(3)

(g) Compliance

Comply with this AD within the compliance times specified, unless already done (compliance with AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998)).

Note 1 to paragraph (g) of this AD: This AD does not require any actions over that already required by AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998). This AD clarifies the FAA's intention that if a sealed wing lift strut assembly is installed as a replacement part, the repetitive inspection requirement is terminated only if the seal is never broken. Also, if the seal is broken, then that wing lift strut becomes subject to continued repetitive inspections. We did not intend to promote drilling holes into or otherwise unsealing a sealed strut, nor did we intend to preclude a proper maintenance action that may temporarily unseal a sealed strut if all appropriate issues are considered, such as static strength, fatigue, material effects, immediate and long-term (internal and external) corrosion protection, resealing methods, etc.

(h) Remove Wing Lift Struts

Within 1 calendar month after February 8, 1999 (the effective date retained from AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998)), or within 24 calendar months after the last inspection done in accordance with AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993) (which was superseded by AD 99–01–05), whichever occurs later, remove the wing lift struts following Piper Aircraft Corporation Mandatory Service Bulletin (Piper MSB) No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10 1989, as applicable. Before further flight after the removal, do one of the actions in either paragraph (i)(1), (i)(2), (j)(1), (j)(2), or (j)(3) of this AD, including all subparagraphs.

(i) Inspect Wing Lift Struts

(1) Before further flight after the removal required in paragraph (h) of this AD, inspect each wing lift strut for corrosion and perceptible dents following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10 1989, as applicable.

(i) *If no corrosion is externally visible and no perceptible dents are found on any wing lift strut during the inspection required in paragraph (i)(1) of this AD,* before further flight, apply corrosion inhibitor to each wing lift strut. Apply the corrosion inhibitor following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10 1989, as applicable. Repetitively thereafter inspect each wing lift strut at intervals not to exceed 24 calendar months following the procedures in paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(ii) *If external corrosion or perceptible dents are found on any wing lift strut during the inspection required in paragraph (i)(1) of this AD or during any repetitive inspection required in paragraph (i)(1)(i) of this AD,* before further flight, replace the affected wing lift strut with one of the replacement options specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD. Do the replacement following the procedures specified in those paragraphs, as applicable.

(2) Before further flight after the removal required in paragraph (h) of this AD, inspect each wing lift strut for corrosion following the procedures in the Appendix to this AD. This inspection must be done by a Level 2 or Level 3 inspector certified using the guidelines established by the American Society for Non-destructive Testing, or MIL–STD–410.

(i) *If no external corrosion is found on any wing lift strut during the inspection required in paragraph (i)(2) of this AD and all requirements in the Appendix to this AD are met,* before further flight, apply corrosion inhibitor to each wing lift strut. Apply the corrosion inhibitor following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10, 1989, as applicable. Repetitively thereafter inspect each wing lift strut at intervals not to exceed 24 calendar months following the procedures in paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(ii) *If external corrosion is found on any wing lift strut during the inspection required paragraph (i)(2) of this AD or during any repetitive inspection required in paragraph (i)(2)(i) of this AD, or if any requirement in the Appendix of this AD is not met,* before further flight after any inspection in which corrosion is found or the Appendix requirements are not met, replace the affected wing lift strut with one of the replacement options specified in paragraph (j)(1), (j)(2), or (j)(3) of this AD. Do the replacement following the procedures specified in those paragraphs, as applicable.

(j) Wing Lift Strut Replacement Options

(1) Install original equipment manufacturer (OEM) part number wing lift struts (or FAA-approved equivalent part numbers) that have been inspected following the procedures in

either paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs, and are found to be airworthy. Do the installations following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10, 1989, as applicable. Repetitively thereafter inspect the newly installed wing lift struts at intervals not to exceed 24 calendar months following the procedures in either paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(2) Install new sealed wing lift strut assemblies (these sealed wing lift strut assemblies also include the wing lift strut forks) following Piper MSB No. 528D, dated October 19, 1990, and Piper MSB No. 910A, dated October 10, 1989, as applicable. Installing one of these new sealed wing lift strut assemblies terminates the repetitive inspection requirements in paragraphs (i) and (l) of this AD, including all sub paragraphs, for that wing lift strut assembly.

(3) Install F. Atlee Dodge wing lift strut assemblies following F. Atlee Dodge Aircraft Services, Inc. Installation Instructions No. 3233–I for Modified Piper Wing Lift Struts Supplemental Type Certificate (STC) SA4635NM, dated February 1, 1991. Repetitively thereafter inspect the newly installed wing lift struts at intervals not to exceed 60 calendar months following the procedures in paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(k) Remove Wing Lift Strut Forks

For all affected airplane models, except for Models PA–25, PA–25–235, and PA–25–260 airplanes, within the next 100 hours time-in-service (TIS) after February 8, 1999 (the effective date retained from AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998)) or within 500 hours TIS after the last inspection done in accordance with AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993) (which was superseded by AD 99–01–05), whichever occurs later, remove the wing lift strut forks (unless already replaced in accordance with paragraph (j)(2) of this AD). Do the removal following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10, 1989, as applicable. Before further flight after the removal, do one of the actions in either paragraph (l) or (m) of this AD, including all subparagraphs.

(l) Inspect and Replace Wing Lift Strut Forks

Before further flight after the removal required in paragraph (k) of this AD, inspect the wing lift strut forks for cracks using magnetic particle procedures, such as those contained in FAA Advisory Circular (AC) 43.13–1B, Chapter 5, which can be found at *http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/99C827DB9BAAC81B86256B4500596C4E?OpenDocument&Highlight=43.13-1b.* Repetitively thereafter inspect at intervals not to exceed 500 hours TIS until the replacement time requirement specified in paragraph (l)(2) or (l)(3) of this AD is reached provided no cracks are found.

(1) *If cracks are found during any inspection required in paragraph (l) of this AD or during any repetitive inspection required in paragraph (l)(2) or (l)(3) of this AD,* before further flight, replace the affected wing lift strut forks with one of the replacement options specified in paragraph (m)(1), (m)(2), (m)(3), or (m)(4) of this AD. Do the replacement following the procedures specified in those paragraphs, as applicable.

(2) *If no cracks are found during the initial inspection required in paragraph (l) of this AD and the airplane is currently equipped with floats or has been equipped with floats at any time during the previous 2,000 hours TIS since the wing lift strut forks were installed,* at or before accumulating 1,000 hours TIS on the wing lift strut forks replace the wing lift strut forks with one of the replacement options specified in paragraph (m)(1), (m)(2), (m)(3), or (m)(4) of this AD. Do the replacement following the procedures specified in those paragraphs, as applicable. Repetitively thereafter inspect the newly installed wing lift strut forks at intervals not to exceed 500 hours TIS following the procedures specified in paragraph (l) of this AD, including all subparagraphs.

(3) *If no cracks are found during the initial inspection required in paragraph (l) of this AD and the airplane has never been equipped with floats during the previous 2,000 hours TIS since the wing lift strut forks were installed,* at or before accumulating 2,000 hours TIS on the wing lift strut forks, replace the wing lift strut forks with one of the replacement options specified in paragraph (m)(1), (m)(2), (m)(3), or (m)(4) of this AD. Do the replacement following the procedures specified in those paragraphs, as applicable. Repetitively thereafter inspect the newly installed wing lift strut forks at intervals not to exceed 500 hours TIS following the procedures specified in paragraph (l) of this AD, including all subparagraphs.

(m) Wing Lift Strut Fork Replacement Options

(1) Install new OEM part number wing lift strut forks of the same part numbers of the existing part (or FAA-approved equivalent part numbers) that were manufactured with rolled threads. Lift strut forks manufactured with machine (cut) threads are not to be used. Do the installations following Piper MSB No. 528D, dated October 19, 1990, or Piper MSB No. 910A, dated October 10, 1989, as applicable. Repetitively thereafter inspect the newly installed wing lift strut forks at intervals not to exceed 500 hours TIS following the procedures specified in paragraph (l)(1) of this AD, including all subparagraphs.

(2) Install new sealed wing lift strut assemblies (these sealed wing lift strut assemblies also include the wing lift strut forks) following Piper MSB No. 528D, dated October 19, 1990, and Piper MSB No. 910A, dated October 10, 1989, as applicable. This installation may have already been done through the option specified in paragraph (j)(2) of this AD. Installing one of these new sealed wing lift strut assemblies terminates the repetitive inspection requirement in paragraphs (i) and (l) of this AD, including all sub paragraphs, for that wing lift strut assembly. Installing one of these new sealed wing lift strut assemblies terminates the repetitive replacement requirement in paragraph (1) of this AD, including all sub paragraphs, for that wing lift strut.

(3) *For the airplanes specified below,* install Jensen Aircraft wing lift strut fork assemblies specified below in the applicable STC following Jensen Aircraft Installation Instructions for Modified Lift Strut Fitting. Installing one of these wing lift strut fork assemblies terminates the repetitive inspection requirement of this AD only for that wing lift strut fork. Repetitively inspect each wing lift strut as specified in paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(i) For Models PA–12 and PA–12S airplanes: STC SA1583NM;

(ii) For Model PA–14 airplanes: STC SA1584NM;

(iii) For Models PA–16 and PA–16S airplanes: STC SA1590NM;

(iv) For Models PA–18, PA–18S, PA–18 ''105'' (Special), PA–18S ''105'' (Special), PA–18A, PA–18 ''125'' (Army L–21A), PA–18S ''125'', PA–18AS ''125'', PA–18 ''135'' (Army L–21B), PA–18A ''135'', PA–18S ''135'', PA–18AS ''135'', PA–18 ''150'', PA–18A ''150'', PA–18S ''150'', PA–18AS ''150'', PA–18A (Restricted), PA–18A ''135'' (Restricted), and PA–18A ''150'' (Restricted) airplanes: STC SA1585NM;

(v) For Models PA–20, PA–20S, PA–20 ''115'', PA–20S ''115'', PA–20 ''135'', and PA–20S ''135'' airplanes: STC SA1586NM; and

(vi) For Model PA–22 airplanes: STC SA1587NM.

(4) Install F. Atlee Dodge wing lift strut assemblies following F. Atlee Dodge Installation Instructions No. 3233–I for Modified Piper Wing Lift Struts (STC SA4635NM), dated February 1, 1991. This installation may have already been done in accordance paragraph (j)(3) of this AD. Installing these wing lift strut assemblies terminate the repetitive inspection requirements of this AD for the wing lift strut fork only. Repetitively inspect the wing lift struts as specified in paragraph (i)(1) or (i)(2) of this AD, including all subparagraphs.

(n) Install Placard

(1) Within 1 calendar month after February 8, 1999 (the effective date retained from AD 99–01–05, amendment 39–10972 (63 FR 72132, December 31, 1998)), or within 24 calendar months after the last inspection required by AD 93–10–06 (58 FR 29965, May 25, 1993) (which was superseded by AD 99–01–05), whichever occurs later, and before further flight after any replacement of a wing lift strut assembly required by this AD, do one of the following:

(i) Install ''NO STEP'' decal, Piper (P/N) 80944–02, on each wing lift strut approximately 6 inches from the bottom of the wing lift strut in a way that the letters can be read when entering and exiting the airplane; or

(ii) Paint the words ''NO STEP'' approximately 6 inches from the bottom of the wing lift struts in a way that the letters can be read when entering and exiting the airplane. Use a minimum of 1-inch letters using a color that contrasts with the color of the airplane.

(2) The ''NO STEP'' markings required by paragraph (n)(1)(i) or (n)(1)(ii) of this AD must remain in place for the life of the airplane.

(o) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office, (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) AMOCs approved for AD 93–10–06, amendment 39–8586 (58 FR 29965, May 25, 1993) and AD 99–01–05, amendment 39–39–10972 (63 FR 72132, December 31, 1998) are approved as AMOCs for this AD.

(p) Related Information

(1) For more information about this AD, contact Gregory K. Noles, Aerospace Engineer, FAA, Atlanta ACO, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

(2) For service information identified in this AD, contact Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; Internet: *www.piper.com.* Copies of the instructions to the F. Atlee Dodge supplemental type certificate (STC) and information about the Jensen Aircraft STCs may be obtained from F. Atlee Dodge, Aircraft Services, LLC., 6672 Wes Way, Anchorage, Alaska 99518–0409, Internet: *www.fadodge.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

APPENDIX TO DOCKET NO. FAA–2013–0023

Procedures and Requirements for Ultrasonic Inspection of Piper Wing Lift Struts

Equipment Requirements

1. A portable ultrasonic thickness gauge or flaw detector with echo-to-echo digital thickness readout capable of reading to 0.001-inch and an A-trace waveform display will be needed to do this inspection.

2. An ultrasonic probe with the following specifications will be needed to accomplish this inspection: 10 MHz (or higher), 0.283-inch (or smaller) diameter dual element or delay line transducer designed for thickness gauging. The transducer and ultrasonic system shall be capable of accurately measuring the thickness of AISI 4340 steel down to 0.020-inch. An accuracy of +/− 0.002-inch throughout a 0.020-inch to 0.050-inch thickness range while calibrating shall be the criteria for acceptance.

3. Either a precision machined step wedge made of 4340 steel (or similar steel with equivalent sound velocity) or at least three shim samples of same material will be needed to accomplish this inspection. One thickness of the step wedge or shim shall be less than or equal to 0.020-inch, one shall be greater than or equal to 0.050-inch, and at least one other step or shim shall be between these two values.

4. Glycerin, light oil, or similar non-water based ultrasonic couplants are recommended in the setup and inspection procedures. Water-based couplants, containing appropriate corrosion inhibitors, may be utilized, provided they are removed from both the reference standards and the test item after the inspection procedure is completed and adequate corrosion prevention steps are then taken to protect these items.

- **Note:** Couplant is defined as ''a substance used between the face of the transducer and test surface to improve transmission of ultrasonic energy across the transducer/strut interface.''
- **Note:** If surface roughness due to paint loss or corrosion is present, the surface should be sanded or polished smooth before testing to assure a consistent and smooth surface for making contact with the transducer. Care shall be taken to remove a minimal amount of structural material. Paint repairs may be necessary after the inspection to prevent further corrosion damage from occurring. Removal of surface irregularities will enhance the accuracy of the inspection technique.

Instrument Setup

1. Set up the ultrasonic equipment for thickness measurements as specified in the instrument's user's manual. Because of the variety of equipment available to perform ultrasonic thickness measurements, some modification to this general setup procedure may be necessary. However, the tolerance requirement of step 13 and the record keeping requirement of step 14, must be satisfied.

2. If battery power will be employed, check to see that the battery has been properly charged. The testing will take approximately two hours. Screen brightness and contrast should be set to match environmental conditions.

3. Verify that the instrument is set for the type of transducer being used, i.e. single or dual element, and that the frequency setting is compatible with the transducer.

4. If a removable delay line is used, remove it and place a drop of couplant between the transducer face and the delay line to assure good transmission of ultrasonic energy. Reassemble the delay line transducer and continue.

5. Program a velocity of 0.231-inch/microsecond into the ultrasonic unit unless an alternative instrument calibration procedure is used to set the sound velocity.

6. Obtain a step wedge or steel shims per item 3 of the EQUIPMENT REQUIREMENTS. Place the probe on the thickest sample using couplant. Rotate the transducer slightly back and forth to ''ring'' the transducer to the sample. Adjust the delay and range settings to arrive at an A-trace signal display with the first backwall echo from the steel near the left side of the screen and the second backwall echo near the right of the screen. Note that when a single element transducer is used, the initial pulse and the delay line/steel interface will be off of the screen to the left. Adjust the gain to place the amplitude of the first backwall signal at approximately 80% screen height on the A-trace.

7. ''Ring'' the transducer on the thinnest step or shim using couplant. Select positive half-wave rectified, negative half-wave rectified, or filtered signal display to obtain the cleanest signal. Adjust the pulse voltage, pulse width, and damping to obtain the best signal resolution. These settings can vary from one transducer to another and are also user dependent.

8. Enable the thickness gate, and adjust the gate so that it starts at the first backwall echo and ends at the second backwall echo. (Measuring between the first and second backwall echoes will produce a measurement of the steel thickness that is not affected by the paint layer on the strut). If instability of the gate trigger occurs, adjust the gain, gate level, and/or damping to stabilize the thickness reading.

9. Check the digital display reading and if it does not agree with the known thickness of the thinnest thickness, follow your instrument's calibration recommendations to produce the correct thickness reading. When a single element transducer is used this will usually involve adjusting the fine delay setting.

10. Place the transducer on the thickest step of shim using couplant. Adjust the thickness gate width so that the gate is triggered by the second backwall reflection of the thick section. If the digital display does not agree with the thickest thickness, follow your instruments calibration recommendations to produce the correct thickness reading. A slight adjustment in the velocity may be necessary to get both the thinnest and the thickest reading correct. Document the changed velocity value.

11. Place couplant on an area of the lift strut which is thought to be free of corrosion and ''ring'' the transducer to surface. Minor adjustments to the signal and gate settings may be required to account for coupling improvements resulting from the paint layer. The thickness gate level should be set just high enough so as not to be triggered by irrelevant signal noise. An area on the upper surface of the lift strut above the inspection area would be a good location to complete this step and should produce a thickness reading between 0.034-inch and 0.041-inch.

12. Repeat steps 8, 9, 10, and 11 until both thick and thin shim measurements are within tolerance and the lift strut measurement is reasonable and steady.

13. Verify that the thickness value shown in the digital display is within +/− 0.002-inch of the correct value for each of the three or more steps of the setup wedge or shims. Make no further adjustments to the instrument settings.

14. Record the ultrasonic versus actual thickness of all wedge steps or steel shims available as a record of setup.

Inspection Procedure

1. Clean the lower 18 inches of the wing lift struts using a cleaner that will remove all dirt and grease. Dirt and grease will adversely affect the accuracy of the inspection technique. Light sanding or polishing may also be required to reduce surface roughness as noted in the EQUIPMENT REQUIREMENTS section.

2. Using a flexible ruler, draw a 1/4-inch grid on the surface of the first 11 inches from the lower end of the strut as shown in Piper Service Bulletin No. 528D or 910A, as applicable. This can be done using a soft (#2) pencil and should be done on both faces of the strut. As an alternative to drawing a complete grid, make two rows of marks spaced every 1/4-inch across the width of the strut. One row of marks should be about 11 inches from the lower end of the strut, and the second row should be several inches away where the strut starts to narrow. Lay the flexible ruler between respective tick marks of the two rows and use tape or a rubber band to keep the ruler in place. See Figure 1.

3. Apply a generous amount of couplant inside each of the square areas or along the edge of the ruler. Re-application of couplant may be necessary.

4. Place the transducer inside the first square area of the drawn grid or at the first 1/4-inch mark on the ruler and ''ring'' the transducer to the strut. When using a dual element transducer, be very careful to record the thickness value with the axis of the transducer elements perpendicular to any curvature in the strut. If this is not done, loss of signal or inaccurate readings can result.

5. Take readings inside each square on the grid or at 1/4-inch increments along the ruler and record the results. When taking a thickness reading, rotate the transducer slightly back and forth and experiment with the angle of contact to produce the lowest thickness reading possible. Pay close attention to the A-scan display to assure that the thickness gate is triggering off of maximized backwall echoes.

• **Note:** A reading shall not exceed .041 inch. If a reading exceeds .041-inch, repeat steps 13 and 14 of the INSTRUMENT SETUP section before proceeding further.

6. If the A-trace is unsteady or the thickness reading is clearly wrong, adjust the signal gain and/or gate setting to obtain reasonable and steady readings. If any instrument setting is adjusted, repeat steps 13 and 14 of the INSTRUMENT SETUP section before proceeding further.

7. In areas where obstructions are present, take a data point as close to the correct area as possible.

• **Note:** The strut wall contains a fabrication bead at approximately 40% of the strut chord. The bead may interfere with accurate measurements in that specific location.

8. A measurement of 0.024-inch or less shall require replacement of the strut prior to further flight.

9. If at any time during testing an area is encountered where a valid thickness measurement cannot be obtained due to a loss of signal strength or quality, the area shall be considered suspect. These areas may have a remaining wall thickness of less than 0.020-inch, which is below the range of this setup, or they may have small areas of localized corrosion or pitting present. The latter case will result in a reduction in signal strength due to the sound being scattered from the rough surface and may result in a signal that includes echoes from the pits as well as the backwall. The suspect area(s) shall be tested with a Maule ''Fabric Tester'' as specified in Piper Service Bulletin No. 528D or 910A.

10. Record the lift strut inspection in the aircraft log book.

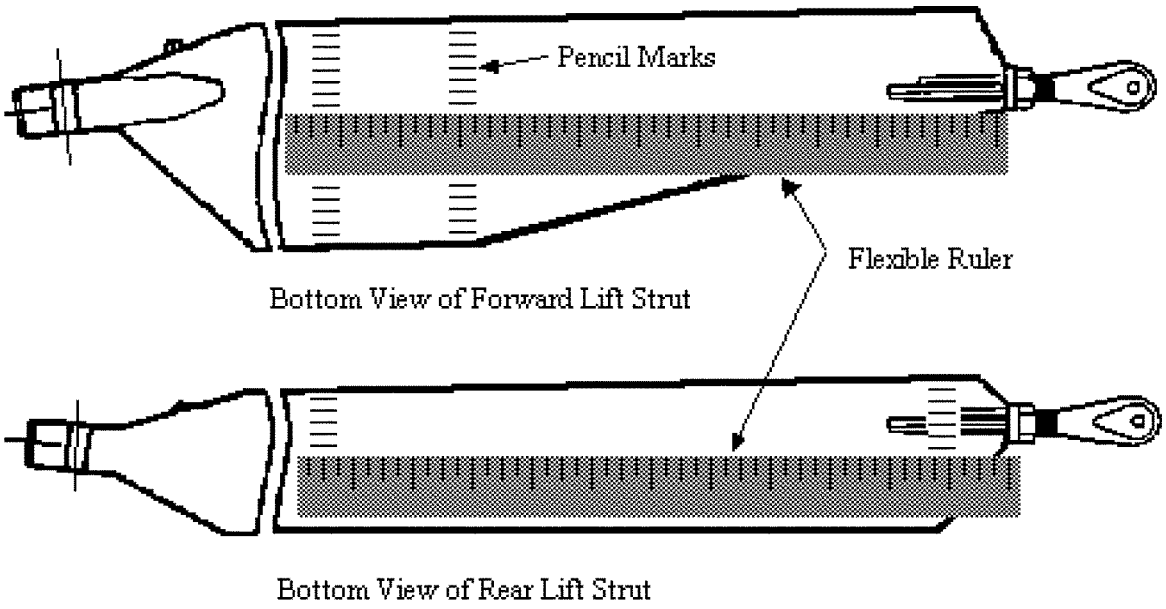

Figure 1

Issued in Kansas City, Missouri, on January 10, 2013.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–00807 Filed 1–15–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1318; Directorate Identifier 2012–NM–104–AD]

RIN 2120–AA64

Airworthiness Directives; the Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–200B, 747–300, 747–400, 747–400D, 747–400F series airplanes, and Model 767 series airplanes, powered by General Electric (GE) CF6–80C2 engines. This proposed AD was prompted by reports of failure of the electro-mechanical brake flex shaft (short flexshaft) of the thrust reverser actuation system (TRAS). This proposed AD would require replacing the short flexshaft on each engine with a new short flexshaft, testing of the electro-mechanical brake and center drive unit (CDU) cone brake to verify the holding torque, and performing related investigative and corrective actions if necessary. We are proposing this AD to prevent an uncommanded in-flight thrust reverser deployment and consequent loss of control of the airplane.

DATES: We must receive comments on this proposed AD by March 4, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tung Tran, Aerospace Engineer, Propulsion Branch, ANM–140S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6505; fax: 425–917–6590; email: *Tung.Tran@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1318; Directorate Identifier 2012–NM–104–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received multiple reports of failure of the short flexshaft of the TRAS on Model 747 and 767 airplanes powered with GE CF6–80C2 engines. The TRAS brake was installed as a third lock to prevent an uncommanded thrust reverser deployment on Model 747 and 767 airplanes powered by GE CF6–80C2 engines. The failed short flexshafts were found to have cores that had become sheared and unbraided. A new short flexshaft design has been developed that incorporates a better end fitting attachment and a larger core diameter with the core wound specifically for use on a left and right thrust reverser half to increase its resistance to failure. We are proposing this AD to prevent an uncommanded in-flight thrust reverser deployment and consequent loss of control of the airplane.

Other Related Rulemaking

On August 13, 2003, we issued AD 2003–16–16, Amendment 39–13269 (68 FR 51439, August 27, 2003), for Model 747–400 series airplanes equipped with GE Model CF6–80C2 series engines. AD 2003–16–16 requires repetitive tests of the cone brake of the CDU of the thrust reversers, and corrective actions if necessary; installation of a TRAS lock and various related modifications and installations. Following installation of the TRAS lock, this action also requires repetitive functional tests of the TRAS lock, and corrective action if necessary.

On July 18, 2000, we issued AD 2000–15–04, Amendment 39–11833 (65 FR 47252, August 2, 2000), for Model 747–200 and –300 series airplanes equipped with GE Model CF6–80C2 series engines with Power Management Control engine controls. AD 2000–15–04 requires various inspections and functional tests to detect discrepancies of the thrust reverser control and indication system, and correction of any discrepancy found; and installation of a terminating modification, and repetitive functional tests of that installation, and repair, if necessary.

On April 26, 2000, we issued AD 2000–09–04, Amendment 39–11712 (65 FR 25833, May 4, 2000), for Model 767 series airplanes equipped with GE Model CF6–80C2 series engines. AD 2000–09–04 requires tests, inspections, and adjustments of the thrust reverser system; and installation of a terminating modification, and repetitive follow-on actions.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 747–78A2185, dated October 26, 2010; and Boeing Alert Service Bulletin 767–78A0100, dated October 26, 2010. This service information describes procedures for replacing the short flexshaft of each thrust reverser

half of each engine with a new short flexshaft.

We reviewed Boeing Service Bulletin 747–78A2166, Revision 3, dated July 29, 2004 (for Model 747 airplanes); Boeing Alert Service Bulletin 767–78A0081, Revision 2, dated April 19, 2001 (for Model 767–200, –300, and –300F airplanes); and Boeing Alert Service Bulletin 767–78A0088, dated April 19, 2001 (for Model 767–400ER airplanes). This service information describes a functional test of the electro-mechanical brake and CDU cone brake to verify the holding torque, and related investigative and corrective actions if necessary.

The related investigative action for the electro-mechanical brake is a general visual inspection of the short flexshaft for twisting, breaking, or other damage.

The corrective action for the electro-mechanical brake is replacement of the long flexshaft between the CDU and the upper angle gearbox with a new flexshaft; replacement of the short flexshaft between the upper angle gearbox and the electro-mechanical brake with a new flexshaft; and replacement of the electromechanical brake with a new electromechanical brake if the required torque value cannot be reached after the previous flexshaft replacements.

The corrective action for a CDU cone brake test failure is replacement of the CDU cone brake with a new CDU cone brake.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 298 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement Model 747 airplanes (72 airplanes).	8 work-hours × $85 per hour = $680	$15,244	$15,924	$1,146,528
Replacement Model 767 airplanes (226 airplanes).	4 work-hours × $85 per hour = $340	7,622	7,962	1,799,412
Functional test Model 747 airplanes (72 airplanes).	12 work-hours × $85 per hour = $1,020	0	1,020	73,440
Functional test Model 767 airplanes (226 airplanes).	12 work-hours × $85 per hour = $1,020	0	1,020	230,520

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2012–1318; Directorate Identifier 2012–NM–104–AD.

(a) Comments Due Date

We must receive comments by March 4, 2013.

(b) Affected ADs

This AD affects AD 2003–16–16, Amendment 39–13269 (68 FR 51439, August 27, 2003); AD 2000–15–04, Amendment 39–11833 (65 FR 47252, August 2, 2000); and AD 2000–09–04, Amendment 39–11712 (65 FR 25833, May 4, 2000).

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, powered by General Electric (GE) CF6–80C2 engines, as identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model 747–200B, 747–300, 747–400, 747–400D, and 747–400F series airplanes, as identified in Boeing Alert Service Bulletin 747–78A2185, dated October 26, 2010.

(2) Model 767–200, –300, –300F, and –400ER series airplanes, as identified in Boeing Alert Service Bulletin 767–78A0100, dated October 26, 2010.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 7830, Thrust reverser.

(e) Unsafe Condition

This AD was prompted by reports of failure of the electro-mechanical brake flex shaft (short flexshaft) of the thrust reverser actuation system (TRAS). We are issuing this AD to prevent an uncommanded in-flight thrust reverser deployment and consequent loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Flexible Drive Shaft Replacement

Within 60 months after the effective date of this AD, replace the short flexshaft on each thrust reverser half of each engine with a new short flexshaft, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–78A2185, dated October 26, 2010; or Boeing Alert Service Bulletin 767–78A0100, dated October 26, 2010; as applicable.

(h) Functional Test

Within 2,000 flight hours after accomplishment of the short flexshaft replacements required by paragraph (g) of this AD: Do a functional test on the electro-mechanical brakes and the cone brake of the center drive unit (CDU) to verify the holding torque, on all thrust reversers and on all engines, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–78A2166, Revision 3, dated July 29, 2004 (for Model 747 airplanes); Boeing Alert Service Bulletin 767–78A0081, Revision 2, dated April 19, 2001 (for Model 767–200, –300, and –300F airplanes); or Boeing Alert Service Bulletin 767–78A0088, dated April 19, 2001 (for Model 767–400ER airplanes). Repeat the functional test thereafter at intervals not to exceed 2,000 flight hours.

(i) Corrective Action

If any functional test required by paragraph (h) of this AD fails: Before further flight, do related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–78A2166, Revision 3, dated July 29, 2004 (for Model 747 airplanes); Boeing Alert Service Bulletin 767–78A0081, Revision 2, dated April 19, 2001 (for Model 767–200, –300, and –300F airplanes); or Boeing Alert Service Bulletin 767–78A0088, dated April 19, 2001 (for Model 767–400ER airplanes); and repeat the applicable test or check until successfully accomplished.

(j) Terminating Actions

(1) Accomplishment of the initial test specified in paragraph (h) of this AD terminates the requirements of paragraph (e) of AD 2003–16–16, Amendment 39–13269 (68 FR 51439, August 27, 2003).

(2) Accomplishment of the initial test specified in paragraph (h) of this AD terminates the requirements of paragraph (g) of AD 2000–15–04, Amendment 39–11833 (65 FR 47252, August 2, 2000).

(3) Accomplishment of the initial test specified in paragraph (h) of this AD terminates the requirements of paragraph (f) of AD 2000–09–04, Amendment 39–11712 (65 FR 25833, May 4, 2000).

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install a flexshaft having part number 3278500–( ) on any airplane.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(m) Related Information

(1) For more information about this AD, contact Tung Tran, Aerospace Engineer, Propulsion Branch, ANM–140S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6505; fax: 425–917–6590; email: *Tung.Tran@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 10, 2013.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–00803 Filed 1–15–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1317; Directorate Identifier 2011–NM–194–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Airplanes Model 737–100, –200, –200C, –300, –400, –500, –600, –700, –700C, –800, and –900 series airplanes. This proposed AD was prompted by a report that the seat track attachment of body station 520 flexible joint is structurally deficient in resisting a 9g forward emergency load condition in certain seating configurations. This proposed AD would require replacing the pivot link assembly on certain seats, and modifying or replacing the seat track link assemblies on certain seats. Also, for certain airplanes, this proposed AD would require installing a new seat track link assembly. We are proposing this AD to prevent seat detachment in an emergency landing, which could cause injury to occupants of the passenger compartment and affect emergency egress.

DATES: We must receive comments on this proposed AD by March 4, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may

review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6483; fax: 425–917–6590; email: *sarah.piccola@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1317; Directorate Identifier 2011–NM–194–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received a report that the seat track attachment of body station 520 flexible joint is structurally deficient in resisting a 9g forward emergency load condition in certain seating configurations. This condition, if not corrected, could result in seat detachment in an emergency landing and cause injury to occupants of the passenger compartment and affect emergency egress.

Relevant Service Information

We reviewed Boeing Service Bulletin 737–53–1244, Revision 5, dated July 27, 2011, for Model 737–600, –700, –700C, –800, and –900 series airplanes. This service bulletin, among other things, describes procedures for installing new, improved pivot link assemblies.

We have also reviewed Boeing Special Attention Service Bulletin 737–53–1260, dated May 7, 2007, for Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This service bulletin describes procedures for modifying or replacing the seat track link assemblies.

Concurrent Service Bulletin

Boeing Special Attention Service Bulletin 737–53–1260, dated May 7, 2007, specifies, for certain airplanes, prior or concurrent accomplishment of Boeing Service Bulletin 737–53–1120, Revision 1, dated May 13, 1993, for modifying or installing new seat track link assemblies.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 1,281 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	U.S. airplanes	Cost on U.S. operators
Replacement or modification.	Up to 41 work-hours × $85 per hour = $3,485.	Up to $15,478	Up to $18,963	1,281	Up to $24,291,603.
Concurrent installation or modification (Groups 1, 2, 4, and 5 airplanes).	Up to 60 work-hours × $85 per hour = $5,100.	Up to $18,089	Up to $23,189	214	Up to $4,962,446.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2012–1317; Directorate Identifier 2011–NM–194–AD.

(a) Comments Due Date

We must receive comments by March 4, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD certificated in any category.

(1) The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, as identified in Boeing Special Attention Service Bulletin 737–53–1260, dated May 7, 2007.

(2) The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes, as identified in Boeing Service Bulletin 737–53–1244, Revision 5, dated July 27, 2011.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report that a Boeing study found that the seat track attachment of body station 520 flexible joint is structurally deficient in resisting a 9 g forward emergency load condition in certain seating configurations. We are issuing this AD to prevent seat detachment in an emergency landing, which could cause injury to occupants of the passenger compartment and affect emergency egress.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repair or Replacement of Seat Track Link Assembly

Within 60 months after the effective date of this AD, do the actions specified in paragraph (g)(1) or (g)(2) of this AD, as applicable.

(1) For Model 737–600, –700, –700C, –800, and –900 series airplanes: Install new, improved pivot link assemblies, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53–1244, Revision 5, dated July 27, 2011.

(2) For Model 737–100, –200, –200C, –300, –400, and –500 series airplanes: Modify or replace, as applicable, the seat track link assembly, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1260, dated May 7, 2007.

(h) Concurrent Actions

For airplanes in Groups 1, 2, 4, and 5, as identified in Boeing Special Attention Service Bulletin 737–53–1260, dated May 7, 2007: Before or concurrently with the accomplishment of the actions specified in paragraph (g)(2) of this AD, install a new seat track link assembly or modify the seat track link assembly, as applicable, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53–1120, Revision 1, dated May 13, 1993.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by The Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Sarah Piccola, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6483; fax: 425–917–6590; email: *sarah.piccola@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 10, 2013.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–00801 Filed 1–15–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 121231747–2747–01]

RIN 0625–AA94

Modification of Regulation Regarding the Extension of Time Limits

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: The Department of Commerce (the Department) proposes to modify its regulation concerning the extension of time limits for submissions in antidumping (AD) and countervailing duty (CVD) proceedings. The modification, if adopted, will clarify that parties may request an extension of time limits before any time limit established under this part expires. This modification will also clarify under which circumstances the Department will grant untimely- filed requests for the extension of time limits.

DATES: To be assured of consideration, comments must be received no later than March 18, 2013.

ADDRESSES: All comments must be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2012–0006, unless the commenter does not have access to the Internet. Commenters who do not have access to the Internet may submit the original and two copies of each set of comments by mail or hand delivery/courier. All

comments should be addressed to Paul Piquado, Assistant Secretary for Import Administration, Room 1870, Department of Commerce, 14th Street and Constitution Ave. NW., Washington, DC 20230. The comments should also be identified by Regulation Identifier Number (RIN) 0625–AA94.

The Department will consider all comments received before the close of the comment period. The Department will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. All comments responding to this notice will be a matter of public record and will be available for inspection at Import Administration's Central Records Unit (Room 7046 of the Herbert C. Hoover Building) and online at *http://www.regulations.gov* and on the Department's Web site at *http://www.trade.gov/ia/.*

Any questions concerning file formatting, document conversion, access on the Internet, or other electronic filing issues should be addressed to Andrew Lee Beller, Import Administration Webmaster, at (202) 482–0866, email address: *webmaster-support@ita.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Joanna Theiss at (202) 482–5052.

SUPPLEMENTARY INFORMATION:

Background

The Department proposes to modify 19 CFR 351.302, which provides for the extension of time limits for submissions in AD and CVD proceedings, and the return of untimely-filed or unsolicited material. Currently, 19 CFR 351.302(b) provides that, unless expressly precluded by statute, the Secretary may, for good cause, extend any time limit established by this part (*i.e.,* Part 351, ''Antidumping and Countervailing Duties''). Section 351.302(c) provides that, before the applicable time limit specified under § 351.301 expires, a party may request an extension pursuant to paragraph (b). Such a request must be in writing, filed in accordance with the relevant regulatory provision, and state the reasons for the request. The extension must be approved in writing. If the Secretary does not extend the time limit, section 351.302(d) sets forth the procedures for the rejection of untimely-filed or unsolicited material.

The Department proposes modifying section 351.302(c) to provide additional certainty to parties participating in AD and CVD proceedings in two important areas. First, the proposed rule will clarify that parties may request an extension of any time limit established by this part, rather than limiting extension requests to submissions under section 351.301, because currently there is no provision in the Department's regulations permitting parties to request extensions of time limits for submissions other than for those established in section 351.301. Thus, this modification makes explicit that parties may request extensions for any time limit established under Part 351. This modification is also consistent with paragraph (b), which provides that the Secretary may, for good cause, extend any time limit established under this part.

Further, the Department proposes modifying section 351.302(c) to clarify and confirm the specific circumstances under which the Department will consider an untimely-filed extension request. The current regulation does not account for extension requests filed after the time limit; section 351.302(c) merely states that ''before the applicable time limit expires * * * a party may request an extension.'' The current regulation also does not address a situation in which a party files an extension request so close to the time limit that the Department does not have the opportunity to respond to the request before the time limit has expired. Untimely-filed extension requests often result in confusion among the parties, difficulties in the Department's organization of its work, and undue expenditure of Departmental resources in addressing such requests. This can impede the Department's ability to conduct AD and CVD proceedings in a timely and orderly manner.

In the vast majority of situations, there should be no reason why a party cannot request an extension prior to the expiration of the applicable time limit, and with adequate opportunity for the Department to consider the request before the time limit expires. It is the Department's view that only in extraordinary circumstances would a party not be able to submit the extension request in a timely manner. Therefore, the Department proposes modifying 19 CFR 351.302(c) to specify that an untimely-filed extension request will not be considered unless the party demonstrates that extraordinary circumstances exist. Only if the Department determines that the party has demonstrated that extraordinary circumstances exist will the Department then consider whether the party has demonstrated that good cause exists for allowing an extension to the time limit pursuant to section 351.302(b).

The Department considers that untimely-filed extension requests encompass those requests that come in after the applicable time limit expires, but the Department requests comment on whether the term ''untimely'' should also include extension requests that are made very close to the applicable time limit. For example, an untimely-filed extension request could be defined as one that is received less than 48 or 24 hours before the applicable time limit expires. The Department also requests comment on whether there should be a separate standard for extension requests for submissions which are due from multiple parties simultaneously, such as case and rebuttal briefs, pursuant to section 351.309. The Department requests comment on whether a separate standard would be useful, to avoid a circumstance in which, for instance, one party requests a last-minute extension to the time limit to file its case brief, with the result that it may review other parties' timely-filed briefs and thus obtain an advantage over the other parties.

Classification

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Initial Regulatory Flexibility Analysis (IRFA)

Pursuant to section 603 of the Regulatory Flexibility Act, the Department has prepared the following IRFA to analyze the potential impact that this proposed rule, if adopted, would have on small entities.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this proposed rule are discussed in the preamble of this document, and not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of all Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

This proposed rule is intended to alter the Import Administration's regulations for AD and CVD proceedings; specifically, to modify the regulation concerning the extension of time limits. The proposed rule would clarify that parties may request the extension of any time limit established under this part, as opposed to the current rule, which only addresses requests for the extension of time limits specified under section 351.301. Further, the proposed rule would establish a standard by which the

Department would consider untimely-filed extension requests because the current regulation only addresses extension requests that are filed before the applicable time limit for the submission expires.

The legal basis for this rule is 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538. No other Federal rules duplicate, overlap, or conflict with this proposed rule.

Number and Description of Small Entities Regulated by the Proposed Action

The proposed rules will apply to any interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, requesting extension of time limits for the submissions in AD and CVD proceedings. This could include any party participating in an AD or CVD proceeding, including exporters and producers of merchandise subject to AD and CVD proceedings and their affiliates, importers of such merchandise, domestic producers of like products, and foreign governments. However, it will only apply to those parties that request an extension of time limits.

Exporters and producers of subject merchandise are rarely U.S. companies. Some exporters and producers of subject merchandise do have U.S. affiliates, some of which may be considered small entities under the appropriate Small Business Administration (SBA) small business size standard. The Department is not able to estimate the number of domestic affiliates of foreign producers or exporters that may be considered small entities, but anticipates, based on its experience in these proceedings, that the number will not be substantial.

Importers may be U.S. or foreign companies, and some of these entities may be considered small entities under the appropriate SBA small business size standard. The Department does not anticipate that the proposed rule will impact a substantial number of small importers because importers of subject merchandise who are not also producers or exporters (or their affiliates) rarely submit material in the course of the Department's AD and CVD proceedings, and those that do tend to be larger entities.

Some domestic producers of like products may be considered small entities under the appropriate SBA small business size standard. Although it is unable to estimate the number of producers that may be considered small entities, the Department does not anticipate that the number affected by the proposed rule will be substantial. Typically, domestic producers that bring a petition or participate actively in an AD or CVD proceeding account for a large amount of the domestic production within an industry, so it is unlikely that many of these domestic producers will be small entities.

In sum, while recognizing that U.S. affiliates of foreign producers or exporters, importers, and domestic producers that submit material in AD and CVD proceedings will likely include some small entities, the Department, based on its experience with these proceedings and the participating parties, does not anticipate that the proposed rule would impact a substantial number of small entities.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The proposed rule will require a party submitting an untimely-filed extension request to demonstrate that extraordinary circumstances exist. This will not amount to a significant burden. Under normal circumstances, a party should be able to submit its extension request in a timely manner because an extension request is a straightforward and usually concise document, identifying only the material to be submitted, the current time limit, the requested extension of that time limit, and the reason for the extension request. In other words, there is no reason to submit extension requests in an untimely manner except under extraordinary circumstances. Thus, if a party files its extension request in an untimely manner, the extraordinary circumstances for submitting the extension request in an untimely manner will be readily available to the party making the untimely extension request.

Description of Any Significant Alternatives to the Proposed Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize any Significant Economic Impact of the Proposed Rule on Small Entities

As required by 5 U.S.C. 603(c), the Department's analysis considered significant alternatives. The alternatives which the Department considered include: (1) The preferred alternative of modifying the rule to establish that parties can request an extension of any time limit established under this part, and that an untimely-filed extension request will not be considered unless the party demonstrates that extraordinary circumstances exist; (2) maintaining the current rule which does not address extension requests for time limits established in provisions other than 19 CFR 351.301 or untimely-filed extension requests; (3) modifying the rule to establish that parties can request an extension of any time limit established under this part, and that untimely-filed extension request will not be considered unless the party demonstrates that good cause exists; and (4) modifying the rule to establish that parties can request an extension of any time limit established under this part, and that untimely-filed extension requests will not be considered.

The Department does not anticipate that the first, preferred alternative will have a significant economic impact on small entities. First, a clarification that parties may request an extension of any time limit established under this part, as opposed to only time limits established by section 351.301, will avoid confusion as to under which provision a party may request an extension. Also, a standard under which untimely-filed extension requests will be considered is not provided under the current regulation, and so the inclusion of a standard will provide clarity to parties appearing before the Department. It does not change the type of material which may be submitted to the Department, nor does it limit a party's ability to request an extension to time limits.

Under alternative two, the Department determined that maintaining the current rule and not addressing extension requests for time limits other than those established under section 351.301, and not including a standard concerning untimely-filed extension requests, will not serve the objective of the proposed rule. If the Department maintained the current rule, then there would be no standard under which the Department would consider untimely-filed extension requests. This would not provide certainty to parties participating in AD and CVD proceedings, and would not address the administrative issues which the Department has encountered. Thus, although this alternative was considered, it was not proposed.

The Department also considered modifying the rule to clarify that a party may request an extension of any time limit established under this part and to establish that the Department will not consider an untimely-filed extension request unless the party demonstrates that good cause exists, described as alternative three. As discussed in the consideration of its preferred alternative, the clarification that an extension request may be of any time limit established by this part serves the objectives of the proposed rule because it makes clear that 19 CFR 351.302(c) applies to extension requests for any

time limit established by this part. The Department next considered a ''good cause'' standard for untimely-filed extension requests. As with the Department's preferred alternative, this alternative establishes a standard under which untimely-filed extension requests will be considered, which is missing from the current rule. The disadvantage to this alternative is that the ''good cause'' exists as the standard by which the Department considers timely-filed extension requests under the current rule. Therefore, a party would have no reason to submit its extension request in a timely manner, because the same standard would apply as if the extension request were filed in an untimely manner. This will not serve the objective of the proposed rule to avoid confusion, will perpetuate the current difficulties in the Department's organization of its work, and will perpetuate the undue expenditure of Departmental resources in addressing extension requests. Thus, it has not been proposed.

The Department also considered modifying the rule to clarify that a party may request an extension of any time limit established under this part and to establish that the Department will not consider any untimely-filed extension requests, described as alternative four. As discussed in the consideration of its preferred alternative, the clarification that an extension request may be of any time limit established by this part serves the objectives of the proposed rule because it makes clear that 19 CFR 351.302(c) applies to extension requests for any time limit established by this part. This alternative would also eliminate the confusion and current difficulties of implementing the current rule by eliminating the source of these issues. However, the Department does recognize that extraordinary, extenuating circumstances can and do arise which may prevent a party from submitting a timely-filed extension request, and, therefore, it considers this alternative to be too inflexible to permit the Department to effectively and fairly administer the unfair trade statutes. Thus, it has not been proposed.

Paperwork Reduction Act

This rule does not require a collection of information for purposes of the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: January 9, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

For the reasons stated, 19 CFR Part 351 is proposed to be amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

■ 1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

■ 2. In § 351.302, revise paragraph (c) as follows:

§ 351.302 Extension of time limits; return of untimely filed or unsolicited material.

* * * * *

(c) *Requests for extension of specific time limit.*

Before the applicable time limit established under this part expires, a party may request an extension pursuant to paragraph (b) of this section. An untimely filed extension request will not be considered unless the party demonstrates that extraordinary circumstances exist. The request must be in writing, filed consistent with § 351.303, and state the reasons for the request. An extension granted to a party must be approved in writing.

* * * * *

[FR Doc. 2013–00833 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2013–0001; Notice No. 132]

RIN 1513–AB98

Proposed Establishment of the Ballard Canyon Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the approximately 7,800-acre ''Ballard Canyon'' viticultural area in Santa Barbara County, California. The proposed viticultural area lies entirely within the larger Santa Ynez Valley viticultural area and the multicounty Central Coast viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

DATES: Comments must be received by March 18, 2013.

ADDRESSES: Please send your comments on this notice to one of the following addresses (please note that TTB has a new address for comments submitted by U.S. mail):

- *Internet: http://www.regulations.gov* (via the online comment form for this notice as posted within Docket No. TTB–2013–0001 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or
- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, selected supporting materials, and any comments that TTB receives about this proposal at *http://www.regulations.gov* within Docket No. TTB–2013–0001. A link to that docket is posted on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 132. You also may view copies of this notice, all related petitions, maps, or other supporting materials, and any comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. Please call 202–453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G St. NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer

deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas and lists the approved American viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and a name and a delineated boundary as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of American viticultural areas. Petitions to establish a viticultural area must include the following:

- Evidence that the area within the proposed viticultural area boundary is nationally or locally known by the viticultural area name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed viticultural area;
- A narrative description of the features of the proposed viticultural area that affect viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed viticultural area distinctive and distinguish it from adjacent areas outside the proposed viticultural area boundary;
- A copy of the appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed viticultural area, with the boundary of the proposed viticultural area clearly drawn thereon; and
- A detailed narrative description of the proposed viticultural area boundary based on USGS map markings.

Ballard Canyon Petition

TTB received a petition from Wesley D. Hagen, a vineyard manager and winemaker, on behalf of 26 other vintners and grape growers in the Ballard Canyon area of California, proposing the establishment of the ''Ballard Canyon'' American viticultural area. The proposed viticultural area contains approximately 7,800 acres, of which approximately 565 acres are dedicated to commercially-producing vineyards. The petition states that there are 10 commercial vineyards located within the proposed viticultural area, with Syrah being the primary grape variety grown. According to the petition, the distinguishing features of the proposed Ballard Canyon viticultural area include wind, temperature, and soils. Unless otherwise noted, all information and data pertaining to the proposed viticultural area contained in this document are from the petition for the proposed Ballard Canyon viticultural area and its supporting exhibits.

The proposed Ballard Canyon viticultural area is located in Santa Barbara County, California, to the west of the town of Ballard. The proposed viticultural area lies at the center of the Santa Ynez Valley viticultural area (27 CFR 9.54) which, in turn, is within the larger multicounty Central Coast viticultural area (27 CFR 9.75). The Santa Ynez Valley viticultural area currently contains two smaller, established viticultural areas: Sta. Rita Hills (27 CFR 9.162), which lies to the west of the proposed viticultural area, and Happy Canyon of Santa Barbara (27 CFR 9.217), which lies to the east of the proposed Ballard Canyon viticultural area. The Sta. Rita Hills and the Happy Canyon of Santa Barbara viticultural areas do not share a boundary or overlap the proposed Ballard Canyon viticultural area.

Name Evidence

The United States Geological Survey's (USGS) Geographical Names Information System (GNIS; *http://geonames.usgs.gov/index.html*) lists ''Ballard Canyon'' as a valley in Santa Barbara County, California. The USGS ''Zaca Creek,'' ''Los Olivos,'' and ''Solvang'' quadrangle maps used to mark the boundary of the proposed viticultural area all indicate a geological feature marked ''Ballard Canyon'' within the proposed viticultural area boundary. The USGS maps also show a paved, light-duty road labeled ''Ballard Canyon Road'' running north and south through the eastern portion of the proposed Ballard Canyon viticultural area. According to the petition, residents refer to property as located in ''Ballard Canyon'' if it is accessible from Ballard Canyon Road or its side streets. The petition also includes evidence that both the canyon and the road are mentioned in official documents of the State of California Water Resources Control Board and the Santa Barbara County Public Works Department.

The petition includes excerpts from articles published in national and international wine periodicals as evidence that the name and location of the proposed Ballard Canyon viticultural area are currently associated with viticulture. A review by wine critic Robert Parker states that, ''[t]he stunning 2009 Malvasia Bianca Larner Vineyard (Ballard Canyon) is just extraordinary.'' (Wine Advocate, No. 190, August 2010; *www.erobertparker.com.*) In an article about Santa Barbara County wines, Sommelier Journal editor Randy Caparoso wrote that, ''[i]n Ballard Canyon, we found something extra: brighter red fruits and sweet spices, revved up by slightly racier acidity.'' (Caparoso, Randy; ''Event Spotlight: 2010 SJ Terroir Experience,'' Sommelier Journal, June 15, 2010, pp. 36–41.) Finally, an article in an October 2003 issue of Wine Enthusiast Magazine about wines of Santa Barbara County mentions that one grape grower attributes ''the juicy ripeness of his monumental Syrah, grown at 1,000 feet in the Ballard Canyon area, to the micro-climate, which he calls 'the best of both cool and warm.'''' (Heimoff, Steve, and Chris Rubin; ''Semi-rustic and Super-chic,'' Wine Enthusiast Magazine, October 1, 2003; *www.winemag.com.*)

Boundary Evidence

As previously noted, the proposed Ballard Canyon viticultural area lies entirely within the Santa Ynez Valley viticultural area, which, in turn, lies within the larger, multicounty Central Coast viticultural area. The proposed viticultural area does not overlap with any other existing or proposed viticultural area.

The region within the proposed Ballard Canyon viticultural area is comprised of steep north-south ranging slopes and maze-like canyons, with Ballard Canyon forming a crescent within the eastern portion. Elevations range from 400 feet at the southernmost portion of the proposed Ballard Canyon viticultural area to approximately 1,280 feet within the northernmost region. The proposed boundary also encompasses the majority of the Alisal Creek-Santa Ynez River watershed.

The proposed boundary follows a series of elevation contours and straight lines between points marked on the relevant USGS maps. A combination of the 1,000-foot elevation contour line and a series of straight lines between points defines the northern portion of the proposed boundary and approximately follows the northernmost edge of Ballard Canyon. The area to the north of the proposed viticultural area contains maze-like canyons and north-south ranges similar to those within the proposed Ballard Canyon viticultural area but generally has higher elevations and is more exposed to the cooling marine influence and strong breezes that travel from the Pacific Ocean through the adjacent Santa Maria Valley.

The eastern portion of the proposed boundary includes the eastern edge of Ballard Canyon and separates the canyonlands from the lower, flatter Los Olivos basin and Santa Ynez Valley, which lie to the immediate east and northeast of the proposed Ballard Canyon viticultural area. Elevations in this region range from 660 feet in the Santa Ynez Valley to 880 feet near Los Olivos.

The southern portion of the proposed boundary follows the 400-foot elevation contour line, which separates the lower, flatter land near the Santa Ynez River from the higher, more rugged canyonlands located within the proposed Ballard Canyon viticultural area. The elevations south of the proposed viticultural area are lower than within the proposed viticultural area, with elevations ranging from 280 feet along the Santa Ynez River to 400 feet near the southernmost portion of the proposed Ballard Canyon viticultural area boundary line.

The western portion of the proposed boundary follows the 600-foot elevation contour line and several straight lines drawn between points to encompass the Alisal Creek-Santa Ynez River watershed. The western portion of the proposed boundary separates the north-south ranges within the proposed Ballard Canyon viticultural area from the east-west ranges to the west. The east-west orientation of the hills and canyons to the west of the proposed Ballard Canyon viticultural area allows more of the cooling marine influence to travel from the Pacific Ocean into this area, bringing stronger breezes, cooler daytime temperatures, and warmer nighttime temperatures than within the proposed Ballard Canyon viticultural area.

Distinguishing Features

The distinguishing features of the proposed Ballard Canyon viticultural area include wind, temperature, and soils.

Wind

To the west of the proposed Ballard Canyon viticultural area are the Purisima, Santa Rita, and Santa Rosa Hills. These mountain ranges run west to east from Lompoc to Buellton and form a ''throat'' that allows winds from the Pacific Ocean to flow inland and through the Sta. Rita Hills viticultural area. However, just east of the Sta. Rita Hills viticultural area and just west of the proposed Ballard Canyon viticultural area, the mountains are aligned in a north-south orientation. These north-south mountains shelter the proposed Ballard Canyon viticultural area from the strongest winds blowing from the west.

The petition provides a summary of average monthly wind and gust speeds in miles per hour (mph) from within the proposed Ballard Canyon viticultural area, as well as from areas to the north (Foxen Canyon), to the east (Happy Canyon of Santa Barbara viticultural area), to the south (Solvang), and to the west (Sta. Rita Hills viticultural area) of the proposed viticultural area. Data was collected from weather stations within the various locations from 2005 through 2009. Winds were measured each year from April through October, which is the grape growing season. The petition also notes that July, August, and September are the critical ripening months for vineyards in the Central Coast region of California, when climate can most affect grape production. TTB prepared the table below using data provided in the petition.

Region	Proposed Ballard Canyon viticultural area	Foxen Canyon (North)	Happy Canyon of Santa Barbara viticultural area (East)	Solvang (South)	Sta. Rita Hills viticultural area (West)
April–October (growing season)					
Average wind speed (miles per hour)	1.37	2.87	1.67	1.72	4.51
Average gust speed (miles per hour)	11.97	15.16	12.63	12.1	17.54
July–September (peak growing season)					
Average wind speed (miles per hour)	0.93	2.1	1.1	1.8	3.7
Average gust speed (miles per hour)	10.5	13.5	10.4	11.9	15.5

As shown in the table, the average growing season wind and gust speeds are lower within the proposed Ballard Canyon viticultural area than in the surrounding areas, with significant differences in wind and gust speeds evident from those in Sta. Rita Hills viticultural area to the west and Foxen Canyon to the north. The petition attributes the lower wind speeds within the proposed Ballard Canyon viticultural area to the north-south mountain ranges that block the stronger winds from the Pacific Ocean. The east-west coastal ''throat'' that funnels winds inland from the Pacific Ocean lies in the heart of the Sta. Rita Hills viticultural area and brings the strongest winds into

that region. Foxen Canyon has north-south ranges similar to the proposed viticultural area; however, the adjacent Santa Maria Valley to the north channels more of the Pacific Ocean winds into the Foxen Canyon region.

According to the petition, low wind and gust speeds have a positive effect on viticulture within the proposed Ballard Canyon viticultural area. Constant winds and strong gusts cause the stomas on the leaves to close to prevent moisture loss; this reduces a vine's ability to photosynthesize efficiently, resulting in less energy and food for the vine. By contrast, a lack of persistently strong winds or gusts allows the stomas to stay open and the grapevines to photosynthesize more efficiently. As a result, the grapes are able to achieve high phenolic ripeness, the peak concentration of compounds (phenols) within the skin, seeds, stems, and pulp of the grape which contribute to the color, flavor, and aroma of the wine.

Temperature

The north-south mountain ranges of the proposed Ballard Canyon viticultural area shelter the proposed viticultural area from the marine influence that affects the areas to the west, north and south. As a result, the temperatures within the proposed Ballard Canyon viticultural area are generally warmer during the day and cooler at night than the areas to the west, north and south. The area to the east of the proposed Ballard Canyon viticultural area, however, is significantly warmer due to a lower marine influence resulting from its more inland location.

The petition provides a summary of high and low temperatures and growing degree day (GDD) [1] data gathered during the growing season (April through October) from 2005 through 2009. The petition also addresses the impact of the variation in temperature between the daytime high and nighttime low (diurnal shift) on viticulture within the proposed viticultural area, but did not calculate the shift. TTB calculated the diurnal shifts and included the information in the table below. The data represent points located within the proposed Ballard Canyon viticultural area, as well as points to the north, east, south, and west of the proposed viticultural area.

Region	Proposed Ballard Canyon viticultural area	Foxen Canyon (North)	Happy Canyon of Santa Barbara viticultural area (East)	Solvang (South)	Sta. Rita Hills viticultural area (West)
Average growing season GDD units	2916.58	2823.2	3139.5	2762.03	2176.14
April–October (growing season)					
Average high temperature	82.6	79.2	84.7	82.2	74.9
Average low temperature	48.9	50.2	49.0	52.5	50.0
Diurnal shift	33.7	29.0	35.7	29.7	24.9
July–September (peak growing season)					
Average high temperature	88.7	85.0	91.1	88.8	78.3
Average low temperature	51.5	53.2	52.5	57.7	53.2
Diurnal shift	37.2	31.8	38.6	31.3	25.1

The data in the table show that the most significant difference in GDD units exists between the proposed viticultural area and the Sta. Rita Hills viticultural area to the west, where the cooling marine influence results in 25 percent fewer GDD units than within the proposed viticultural area. The high GDD unit accumulation within the proposed Ballard Canyon viticultural area indicates that the growing season temperatures rise far enough above the key 50 degrees Fahrenheit (F) mark to allow adequate time for grapes to develop and ripen fully. Heat accumulation strongly influences varietal planting decisions, making the proposed viticultural area particularly suited to warm-weather grape varieties such as Syrah, which is the primary grape variety grown in the proposed viticultural area.

The data in the table also show that the proposed Ballard Canyon viticultural area has warmer days and cooler nights during the growing season than most of the surrounding area, which results in large diurnal shifts. The most significant differences in diurnal shifts are between the proposed viticultural area and Foxen Canyon to the north, Solvang to the south, and the Sta. Rita Hills viticultural area to the east, the differences being more pronounced during the peak growing season. According to the petition, large diurnal shifts like those found within the proposed viticultural area produce desirably high levels of sugar and acid in grapes because the daytime heat increases sugar production and the nighttime cooling reduces acid loss.

Soils

More than 95 percent of the acreage within the proposed Ballard Canyon viticultural area contains a unified soil association called the Chamise-Arnold-Crow Hill association. This soil group is defined as gently sloping to very steep, with well drained to somewhat excessively drained sands as well as clay loams on high terraces and uplands. A very small portion of the southern end of the proposed Ballard Canyon viticultural area contains the Positas-Ballard-Santa Ynez association and the Sorrento-Mocho-Camarillo association. The Positas-Ballard-Santa Ynez association is described in the Santa Barbara area soil map as being nearly level to moderately steep, with well drained and moderately well drained fine sandy loams to clay loams on terraces (''Northern Santa Barbara Area, California General Soil Map,'' issued by the United States Department of Agriculture Soil Conservation Service, 1971). The same soil map describes the Sorrento-Mocho-Camarillo association as nearly level to moderately sloping, with well drained to somewhat

[1] In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual GDD, defines climatic regions. One GDD accumulates for each degree Fahrenheit that a day's mean temperature is above 50 degrees, the minimum temperature required for grapevine growth (''General Viticulture,'' by Albert J. Winkler, University of California Press, 1974, pages 61–64).

poorly drained sandy loams to silty clay loams on flood plains and alluvial fans.

The soils of most of the area immediately adjacent to the proposed Ballard Canyon viticultural area are a continuation of the associations found within the proposed viticultural area, but they transition to other dominant soil types. To the north of the proposed viticultural area, the soils transition from the Chamise-Arnold-Crow Hill association to Shedd-Santa Lucia-Diablo and Toomes-Climara associations near the San Rafael Mountains. To the east and south of the proposed viticultural area, the soils begin as the Positas-Ballard-Santa Ynez association and transition to the Toomes-Climara and Shedd-Santa Lucia-Diablo associations. To the southwest, the soils are of the Sorrento-Mocho-Camarillo and Positas-Ballard-Santa Ynez associations near the boundary of the proposed viticultural area and change to Shedd-Santa Lucia-Diablo farther south near the Santa Ynez Mountains. To the west, the soils begin as a continuation of the Chamise-Arnold-Crow Hill and Sorrento-Mocho-Camarillo associations and change to the Marina-Oceano association nearer to the Pacific Ocean.

The soil structure, pH values, and mineral levels of the proposed viticultural area also differ from that of the areas to the east and west. Information on these factors was not available concerning areas to the north and south of the proposed viticultural area. An analysis of soils from four vineyards within the proposed viticultural area indicates the soil profile is consistently a layer of loam on top of a layer of clay, which in turn is on a second layer of loam. By contrast, soils of the Sta. Rita Hills viticultural area, to the west, contain more sand, and soils of the Happy Canyon of Santa Barbara viticultural area, to the east, contain more clay.

The soil analysis of the four vineyards within the proposed Ballard Canyon viticultural area reveals a wide range of soil pH values. Soil pH values affect the ability of grapevines to uptake nutrients, and the analysis notes that the desired pH range for viticulture is 6.5 to 7.5. Moderately acidic soils reduce the ability of the vines to uptake nutrients, resulting in less vigorous vine and leaf growth and the production of berries that have high concentrations of desirable flavors, sugars, and acids. The pH values within the proposed viticultural area range from 5.5 (moderately acidic) to 7.5 (slightly alkaline), with the more acidic soils appearing in the surface portions of the samples and the neutral and alkaline soils appearing at greater depths, where most root activity takes place. By contrast, soil pH values in the Happy Canyon of Santa Barbara viticultural area, to the east, are consistently alkaline (7.25). Soil pH values for the Sta. Rita Hills, to the west, are slightly acidic, with values from 6.1 to 6.7.

With regard to mineral levels within the soils, the analysis reveals that nitrogen levels within the proposed viticultural area are between 1.5 and 13 ppm, with the most common total being 5 ppm. Nitrogen levels in the soils to the west, within the Sta. Rita Hills viticultural area, are also very low.[2] By contrast, to the east, within the Happy Canyon of Santa Barbara viticultural area, nitrogen levels in the soil are very high, with levels two to three times higher than recommended for viticulture, which requires growers to ameliorate their soils in order to achieve a lower, more desirable nitrogen level.[3] The petition notes that the optimal nitrogen level for viticulture is between 4 and 8 ppm, and that low levels of nitrogen in the soil, such as those commonly found within the proposed viticultural area, result in lower vine vigor, smaller berries, and more intensity in the resulting wines.

Potassium levels within the soils of the proposed viticultural area are described as moderately deficient, with levels varying from 70 to 220 ppm and most soil samples having a range from 120 to 160 ppm. The analysis notes the optimal soil potassium level for grape-growing is between 100 to 500 ppm, as this level is sufficient to provide protein synthesis support, but is low enough to prevent overly vigorous vine growth. By contrast, the Sta. Rita Hills viticultural area has soils that are highly deficient in potassium, with levels as low as 1 ppm in some soils, mostly due to the sandy nature of the soils. Potassium levels in the soils of the Happy Canyon of Santa Barbara viticultural area are higher than those of the proposed Ballard Canyon viticultural area, with average soil levels of 200 ppm.

Finally, exchangeable levels of calcium in the soils within the proposed Ballard Canyon viticultural area are between 1,000 and 1,400 ppm, within the range generally preferred for viticulture. According to the petition, calcium affects the thickness of grape skins, with high levels producing thicker skins, lower juice-to-skin ratios during ferment, and wines of deeper color and richness. The soils of the Sta. Rita Hills viticultural area to the west contain higher levels of calcium than the proposed Ballard Canyon viticultural area, around 1,220 ppm, but the lower amounts of clay in the soil in that region limit the ability of the vines to uptake the calcium. The soils of the Happy Canyon of Santa Barbara viticultural area to the east contain calcium levels up to ten times higher than those of the proposed Ballard Canyon viticultural area and also have high clay levels, enabling an efficient transfer of calcium to the vines.

Summary of Distinguishing Features

In summary, the evidence provided in the petition indicated that the geographic features of the proposed Ballard Canyon viticultural area distinguish it from the surrounding regions in each direction. To the north, the winds are stronger, the diurnal shifts in temperature are lower during the peak growing season, and the soils transition to the Shedd-Santa Lucia-Diablo and Toomes-Climara associations. To the east, within the Happy Canyon of Santa Barbara viticultural area, the average temperature and GDD units are higher, and the soils contain more clay and higher levels of nitrogen and potassium. To the south, the winds are stronger, the diurnal shifts in temperature are lower during the peak growing season, and the soils are of the Shedd-Santa Lucia-Diablo and Toomes-Climara associations. To the west, within the Sta. Rita Hills viticultural area, the winds are significantly stronger, the GDD units are fewer and temperatures are significantly lower, the diurnal shifts in temperature are significantly lower during the peak growing season, and the soils are sandier, less acidic, and lower in potassium.

Comparison of the Proposed Ballard Canyon Viticultural Area to the Existing Santa Ynez Valley and Central Coast Viticultural Areas

Santa Ynez Valley Viticultural Area

The Santa Ynez Valley viticultural area was established by T.D. ATF–132, which published in the **Federal Register** on April 15, 1983 (48 FR 16252). The Santa Ynez Valley viticultural area encompasses the Sta. Rita Hills and the Happy Canyon of Santa Barbara viticultural areas, as well as the proposed Ballard Canyon viticultural area.

According to T.D. ATF–132, the Santa Ynez Valley viticultural area is a valley that surrounds the Santa Ynez River and is bounded by the Purisima Hills and

[2] All soil nutrient information for Sta. Rita Hills viticultural area can be found in the soil analysis in Addendum Exhibit 2 of the petition.

[3] All soil nutrient information for the Happy Canyon of Santa Barbara viticultural area can be found in the soil analysis in Addendum Exhibit 1 of the petition.

San Rafael Mountains to the north, Lake Cachuma and the Los Padres National Forest to the east, the Santa Ynez Mountains to the south, and the Santa Rita Hills to the west. Vineyards are planted on elevations ranging from 200 feet along the Santa Ynez River to 1,500 feet in the foothills of the San Rafael Mountains. The Santa Ynez Valley viticultural area has seven major soil associations, but vineyards are primarily planted on soils of the Positas-Ballard-Santa Ynez, Chamise-Arnold-Crow Hill, Shedd-Santa Lucia-Diablo, and Sorrento-Mocho-Camarillo series. The Santa Ynez Valley viticultural area has less marine influence from the Pacific Ocean than the more coastal regions to the west because the hills to the west of the region prevent much of the marine influence from reaching deep into the valley, resulting in a less moderated climate and overall warmer temperatures than those of areas closer to the coast. Even without a heavy marine influence, fog is still common at elevations between 1,000 and 1,200 feet. The valley averages 2,680 GDD units annually, making it a Region II area on the Winkler scale.

The proposed Ballard Canyon viticultural area is located in the center of the Santa Ynez Valley viticultural area and shares some broad characteristics of the larger Santa Ynez Valley viticultural area. Like much of the Santa Ynez Valley viticultural area, the proposed Ballard Canyon viticultural area is sheltered from the strongest marine influence of the Pacific Ocean and is warmer than the coastal regions. However, due to its much smaller size and more inland location, the geographic features of the proposed Ballard Canyon viticultural area are more uniform. The proposed viticultural area is a region of north-south ranging hills and maze-like canyons, compared to the more level topography of the Santa Ynez Valley as a whole. In contrast to the varied soils of the Santa Ynez Valley viticultural area, the proposed Ballard Canyon viticultural area soils are predominately of the Chamise-Arnold-Crow Hill association. In addition, due to its more central location within the Santa Ynez Valley, the proposed viticultural area is also warmer than the western portion of the Santa Ynez Valley (Sta. Rita Hills viticultural area) and cooler than the eastern region (Happy Canyon of Santa Barbara viticultural area).

Central Coast Viticultural Area

The large, 1 million-acre Central Coast viticultural area was established by T.D. ATF–216, which published in the **Federal Register** on October 24, 1985 (50 FR 43128). The Central Coast viticultural area encompasses the California counties of Monterey, Santa Cruz, Santa Clara, Alameda, San Benito, San Luis Obispo, and Santa Barbara, and it contains 27 established American viticultural areas. T.D. ATF–216 describes the Central Coast viticultural area as extending from Santa Barbara to the San Francisco Bay area, and east to the California Coastal Ranges. The only distinguishing feature of the California Coast viticultural area addressed in T.D. ATF–216 is that all of the included counties experience marine climate influence due to their proximity to the Pacific Ocean.

The proposed Ballard Canyon viticultural area, due to its location within Santa Barbara County, is located within the Central Coast viticultural area. Although the north-south ranges of the proposed Ballard Canyon viticultural area block some of the marine influence characteristic of the Central Coast viticultural area, viticulture in the region is still affected by slight breezes and mild gusts from the Pacific Ocean that reach the area during the growing season. The proposed viticultural area has greater uniformity in geographical features such as wind, temperature and soils.

TTB Determination

TTB concludes that the petition to establish the approximately 7,800-acre Ballard Canyon viticultural area merits consideration and public comment, as invited in this notice.

Boundary Description

See the narrative boundary description of the petitioned-for viticultural area in the proposed regulatory text published at the end of this notice.

Maps

The petitioner provided the required maps, and they are listed below in the proposed regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. If TTB establishes this proposed viticultural area, its name, ''Ballard Canyon,'' will be recognized as a name of viticultural significance under 27 CFR 4.39(i)(3). The text of the proposed regulation clarifies this point. Consequently, wine bottlers using the name ''Ballard Canyon'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the viticultural name as an appellation of origin if this proposed rule is adopted as a final rule. TTB does not believe that ''Ballard,'' standing alone, should have viticultural significance if the proposed viticultural area is established, due to the widespread use of ''Ballard'' as a geographical name. GNIS shows the name ''Ballard'' used in reference to over 300 locations in 44 States. Accordingly, the proposed part 9 regulatory text set forth in this document specifies only the full name ''Ballard Canyon'' as a term of viticultural significance for purposes of part 4 of the TTB regulations.

The approval of the proposed Ballard Canyon viticultural area would not affect any existing viticultural area, and any bottlers using ''Santa Ynez Valley'' or ''Central Coast'' as an appellation of origin or in a brand name for wines made from grapes grown within the Santa Ynez Valley or Central Coast viticultural areas would not be affected by the establishment of this new viticultural area. The establishment of the proposed Ballard Canyon viticultural area would allow vintners to use ''Ballard Canyon,'' ''Santa Ynez Valley,'' and ''Central Coast'' as appellations of origin for wines made from grapes grown within the proposed Ballard Canyon viticultural area if the wines meet the eligibility requirements for the appellation.

For a wine to be labeled with a viticultural area name or with a brand name that includes a viticultural area name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with a viticultural area name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the viticultural area name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label.

Different rules apply if a wine has a brand name containing a viticultural area name or other viticulturally significant term that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on whether it

should establish the proposed viticultural area. TTB is also interested in receiving comments on the sufficiency and accuracy of the name, boundary, soils, climate, and other required information submitted in support of the petition. In addition, given the proposed Ballard Canyon viticultural area's location within the existing Santa Ynez Valley and Central Coast viticultural areas, TTB is interested in comments on whether the evidence submitted in the petition regarding the distinguishing features of the proposed viticultural area sufficiently differentiates it from the existing Santa Ynez Valley and Central Coast viticultural areas. TTB is also interested in comments whether the geographic features of the proposed viticultural area are so distinguishable from the surrounding Santa Ynez Valley and Central Coast viticultural areas that the proposed Ballard Canyon viticultural area should no longer be part of those viticultural areas. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed Ballard Canyon viticultural area on wine labels that include the term ''Ballard Canyon'' as discussed above under Impact on Current Wine Labels, TTB is particularly interested in comments regarding whether there will be a conflict between the proposed area name and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed viticultural area will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting a modified or different name for the viticultural area.

Submitting Comments

You may submit comments on this notice by using one of the following three methods (please note that TTB has a new address for comments submitted by U.S. Mail):

- *Federal e-Rulemaking Portal:* You may send comments via the online comment form posted with this notice within Docket No. TTB–2013–0001 on ''Regulations.gov,'' the Federal e-rulemaking portal, at *http://www.regulations.gov.* A direct link to that docket is available under Notice No. 132 on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml.* Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on ''User Guide'' under ''How to Use this Site.''
- *U.S. Mail:* You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.
- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 132 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name as well as your name and position title. If you comment via Regulations.gov, please enter the entity's name in the ''Organization'' blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this notice, selected supporting materials, and any online or mailed comments received about this proposal within Docket No. TTB–2013–0001 on the Federal e-rulemaking portal, Regulations.gov, at *http://www.regulations.gov.* A direct link to that docket is available on the TTB Web site at *http://www.ttb.gov/wine/wine_rulemaking.shtml* under Notice No. 132. You may also reach the relevant docket through the Regulations.gov search page at *http://www.regulations.gov.* For information on how to use Regulations.gov, click on the site's Help or FAQ tabs.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that the Bureau considers unsuitable for posting.

You may also view copies of this notice, all related petitions, maps and other supporting materials, and any electronic or mailed comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact TTB's information specialist at the above address or by telephone at 202–453–2270 to schedule an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act

TTB certifies that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of a viticultural area name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This proposed rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this notice.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, TTB proposes to amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.____ to read as follows:

§ 9.____ Ballard Canyon.

(a) *Name.* The name of the viticultural area described in this section is ''Ballard Canyon''. For purposes of part 4 of this chapter, ''Ballard Canyon'' is a term of viticultural significance.

(b) *Approved maps.* The three United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Ballard Canyon viticultural area are titled:

(1) Los Olivos, CA, 1995;

(2) Zaca Creek, Calif., 1959; and

(3) Solvang, CA, 1995.

(c) *Boundary.* The Ballard Canyon viticultural area is located in Santa Barbara County, California. The boundary of the Ballard Canyon viticultural area is as described below:

(1) The beginning point is on the Los Olivos map at the intersection of State Route 154 and Foxen Canyon Road, section 23, T7N/R31W.

(2) From the beginning point, proceed southwesterly in a straight line approximately 0.3 mile, crossing onto the Zaca Creek map, to the intersection of Ballard Canyon Road and an unnamed, unimproved road known locally as Los Olivos Meadows Drive, T7N/R31W; then

(3) Proceed south-southeasterly in a straight line approximately 1 mile, crossing onto the Los Olivos map, to a marked, unnamed large structure located within a circular-shaped 920-foot contour line in the southwest corner of section 26, T7N/R31W; then

(4) Proceed south-southwesterly in a straight line approximately 1.25 miles, crossing onto the Zaca Creek map, to the marked by the ''Ball'' 801-foot elevation control point, T6N/R31W; then

(5) Proceed south-southwesterly in a straight line approximately 1.45 miles, crossing onto the Solvang map, to a marked, unnamed 775-foot peak, T6N/R31W; then

(6) Proceed south-southwesterly in a straight line approximately 0.55 mile to a marked communication tower'' located within the 760-foot contour line, T6N/R31W; then

(7) Proceed west-southwesterly in a straight line approximately 0.25 mile to the intersection of Chalk Hill Road and an unnamed light-duty road known locally as Mesa Vista Lane, T6N/R31W; then

(8) Proceed west-southwesterly in a straight line approximately 0.6 mile to the southern-most terminus of a marked, unnamed stream known locally as Ballard Creek, T6N/R31W; then

(9) Proceed northerly (upstream) along Ballard Creek approximately 0.35 miles to the creek's intersection with the 400-foot contour line, T6N/R31W; then

(10) Proceed southerly and then northwesterly along the 400-foot contour line approximately 1.5 miles, to the contour line's first intersection with Ballard Canyon Road, T6N/R31W; then

(11) Proceed north-northeasterly in a straight line approximately 1.7 miles, crossing onto the Zaca Creek map, to the western-most intersection of the 800-foot contour line and the T6N/T7N boundary line (approximately 0.9 mile east of U.S Highway 101); then

(12) Proceed west along the T6N/T7N boundary line approximately 0.4 miles to the boundary line's third intersection with the 600-foot contour line (approximately 0.5 mile east of U.S. Highway 101); then

(13) Proceed northerly along the meandering 600-foot elevation contour line to the contour line's intersection with Zaca Creek, T7N/R31W; then

(14) Proceed northeasterly in a straight line for approximately 1.2 miles to the western-most intersection of the southern boundary of the Corral de Quati Land Grant and the 1,000-foot contour line (approximately 0.4 mile east of U.S. Highway 101), T7N/R31W; then

(15) Proceed easterly along the meandering 1,000-foot contour line approximately 1.5 miles to the contour line's third intersection with the southern boundary of the Corral de Quati Land Grant (approximately 0.1 mile west of State Route 154), section 22, T7N/R31W; then

(16) Proceed southeasterly in a straight line approximately 0.8 miles, crossing onto the Los Olivos map, returning to the beginning point.

Signed: January 8, 2013.

John J. Manfreda,

Administrator.

[FR Doc. 2013–00699 Filed 1–15–13; 8:45 am]

BILLING CODE 4810–31–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0001; FRL–9375–4]

Notice of Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before February 15, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: A contact person, with telephone number and email address, is listed at the end of each pesticide petition summary. You may also reach each contact person by mail at Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 346a), requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available online at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerances

1. *PP 2E8068.* (EPA–HQ–OPP–2012–0710). BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide boscalid (BAS 510F); [3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro(1,1′-biphenyl)-2-yl)-], in or on artichoke, globe at 6.0 ppm; berry, low growing, subgroup 13–07G at 4.5 ppm; bushberry, subgroup 13–07B at 13 ppm; caneberry, subgroup 13–07A at 6.0 ppm; endive, Belgium at 5.0 ppm; fruit, citrus, group 10–10 at 1.6 ppm; fruit, pome, group 11–10 at 3.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F, at 3.5 ppm; oilseed, group 20 at 3.5 ppm; persimmon at 7.0 ppm; turnip, greens at 18.0 ppm; vegetable, bulb group 3–07 at 3.0 ppm; vegetable, fruiting, group 8–10 at 1.2 ppm; vegetable, root subgroup 1B, except sugarbeet, at 1.0 ppm. In plants, the parent residue is extracted using an aqueous organic solvent mixture followed by liquid/liquid (L/L) partitioning and a column clean up. Quantitation is by gas chromatography/mass spectrometry (GC/MS). In livestock, the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by L/L partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column clean-up. The parent and acetylated metabolite are quantitated by GC with electron capture detection (ECD). Contact: Andrew Ertman, (703) 308–9367, email address: *ertman.andrew@epa.gov.*

2. *PP 2E8069.* (EPA–HQ–OPP–2012–0549). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate (BF 500–3); expressed as parent compound, in or on artichoke, globe at 3.0 parts per million (ppm); endive, Belgium at 3.0 ppm; and persimmon at 3.0 ppm. In plants, the method of analysis is aqueous organic solvent extraction, column clean up and quantitation by liquid chromatography/tandem mass spectrometry (LC/MS/MS). In animals, the method of analysis involves base hydrolysis, organic extraction, column clean up and quantitation by LC/MS/MS or derivatization (methylation) followed by quantitation by GC/MS. Contact: Andrew Ertman, (703) 308–9367, email address: *ertman.andrew@epa.gov.*

3. *PP 2E8114.* (EPA–HQ–OPP–2012–0903). Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide tricyclazole, 5-methyl-1,2,4-triazolo[3,4-b] benzothiazole, including

its metabolites and degradates, in or on rice at 3.0 ppm. There are adequate validated methods that exist for the quantification of tricyclazole (TCA) and tricyclazole alcohol metabolite (TCA–OH) residues in rice. There is also successful method validation available for multi-residue DFG method S19 for determination of tricyclazole in rice by GS/MS detection. Contact: Erik Kraft, (703) 308–9358, email address: *kraft.erik@epa.gov.*

4. *PP 2E8117.* (EPA–HQ–OPP–2012–0911). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on vegetable, fruiting, group 8–10 at 1.7 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.60 ppm; and berry, low growing, subgroup 13–07G at 0.90 ppm. A practical analytical method is available to monitor and enforce the tolerances of quinoxyfen residues in crops. The analytical method uses a capillary GC and MS detection (GC–MSD). The method is adequate for collecting data and enforcing tolerances for quinoxyfen residues in/on the subject crops. Contact: Sidney Jackson, (703) 305–7610, email address: *jackson.sidney@epa.gov.*

5. *PP 2E8118.* (EPA–HQ–OPP–2012–0912). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR 180.544 for residues of the insecticide methoxyfenozide, (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) including its metabolites and degradates, in or on the raw agricultural commodities under paragraph (a) in or on herb subgroup 19A, except chive at 400 ppm; date at 7 ppm; caneberry subgroup 13–07A at 6 ppm; sorghum, grain, forage at 9 ppm; sorghum, grain, stover at 15 ppm; sorghum, grain, grain at 4 ppm; sorghum, sweet, forage at 9 ppm; sorghum, sweet, stover at 15 ppm; sorghum, sweet, grain at 4 ppm; sorghum, sweet, stalk at 9 ppm; grain, aspirated grain fractions at 80 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed at 0.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1 ppm; berry, low growing, except cranberry, subgroup 13–07G at 1.5 ppm; fruit, pome, group 11–10 at 1.5 ppm; vegetable, fruiting, group 8–10 at 2 ppm; sugar apple at 0.6 ppm; cherimoya at 0.6 ppm; atemoya at 0.6 ppm; custard apple at 0.6 ppm; ilama at 0.6 ppm; soursop at 0.6 ppm; and biriba at 0.6 ppm. Additionally, the petition requested to establish tolerances in 40 CFR 180.544, under paragraph (d)(2) for indirect or inadvertent residues of methoxyfenozide in or on rapeseed subgroup 20A at 1.0 ppm and sunflower subgroup 20B at 1.0 ppm. Per a recent 2012 decision on tolerances, EPA stated adequate single methods are available for tolerance enforcement in primary crops and animal commodities. Analytical methodology for the magnitude of residue studies was based on Dow AgroSciences method GRM 02.25 ''Determination of Residues of Methoxyfenozide in High Moisture Crops by Liquid Chromatography with Tandem Mass Spectrometry Detection''. Contact: Laura Nollen, (703) 305–7390, email address: *nollen.laura@epa.gov.*

6. *PP 2F8058.* (EPA–HQ–OPP–2012–0924). BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide fluxapyroxad, (BAS 700 F); 1 H-Pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-, its metabolites, and degradates, in or on nongrass animal feeds, group 18 at 0.5 ppm; and mint at 0.05 ppm. Independently validated analytical methods have been submitted for analyzing residues of parent BAS 700 F (fluxapyroxad) plus metabolites M700F008, M700F048 and M700F002 with appropriate sensitivity in all the crop and processed commodities for root and tuber vegetables (subgroups 1A, 1C, D), sugar beet tops, legume vegetables including soybean (group 6), foliage of legume vegetables (group 7), fruiting vegetables (group 8), pome fruits (group 11), stone fruits (group 12), cereal grains (group 15), forage, fodder and straw of cereal grains (group 16), cotton, canola (rapeseed), sunflower and peanut and in animal meat, fat, liver and kidney matrices, poultry meat, fat, liver and skin, milk, cream and eggs for which tolerances have been established. Contact: Olga Odiott, (703) 308–9369, email address: *odiott.olga@epa.gov.*

7. *PP 2F8077.* (EPA–HQ–OPP–2012–0829). Monsanto Company, 1300 I Street NW., Suite 450 East, Washington, DC 20005, (a member of the Acetochlor Registration Partnership, (ARP)), requests to establish tolerances in 40 CFR 180.470(a) for residues of the herbicide acetochlor (2-chloro-2′-methyl-6′-ethyl-*N*-ethoxymethyl acetanilide) and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6-methylaniline (HEMA) moiety, to be expressed as acetochlor equivalents, resulting from applications to soil or growing crops, in or on beet, sugar, dried pulp at 0.5 ppm; beet, sugar, molasses at 1.3 ppm; beet, sugar, roots at 0.3 ppm; beet, sugar, tops at 0.8 ppm; peanut at 0.2 ppm; peanut, hay at 6.0 ppm; and peanut, meal at 0.5 ppm. An adequate enforcement method for residues of acetochlor in crops has been approved. Acetochlor and its metabolites are hydrolyzed to either EMA or HEMA, which are determined by high pressure liquid chromatography-oxidative coulometric electrochemical detector (HPLC–OCED) and expressed as acetochlor equivalents. Contact: Hope Johnson, (703) 305–5410, email address: *johnson.hope@epa.gov.*

8. *PP 2F8099.* (EPA–HQ–OPP–2012–0941). Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596, requests to establish tolerances in 40 CFR 180.627 for inadvertent residues of the fungicide fluopicolide, 2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, as an indicator of combined residues of fluopicolide and its metabolite, 2,6-dichlorobenzamide (BAM), in or on corn, field, forage at 0.09 ppm; corn, field, grain at 0.01 ppm; and corn, field, stover at 0.3 ppm, resulting from the proposed use as a fungicide. Additional data included in the petition, to assess potential dietary exposure from P1x and PCA, shows no inadvertent residues of P1x or PCA in the corn grain. Practical analytical methods for detecting and measuring levels of fluopicolide and its metabolites have been developed and validated in/on all appropriate plant and animal matrices. An analytical method for detecting fluopicolide and BAM in field corn matrices has been submitted with this petition. In addition, an analytical method for detecting P1x and PCA in corn grain (for assessing dietary exposure) has been submitted with this petition. Contact: Dominic Schuler, (703) 347–0260, email address: *schuler.dominic@epa.gov.*

9. *PP 2F8106.* (EPA–HQ–OPP–2012–0925). Taminco, Inc., Two Windsor Plaza, Suite 411, Allentown, PA, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide thiram, in or on strawberry at 20 ppm. Strawberry samples were analyzed according to ALS Laboratory Group method MS 133.02 ''The Determination of Mancozeb and/or Other Ethylene-bis-dithiocarbamates (EBDCs) as CS_2 in Plant Tissue by GC/MS''. Detection and quantitation for thiram (as CS_2) were conducted using a GC equipped with a mass spectral

detector (MSD) for determination of CS_2. Contact: Shaunta Hill, (703) 347–8961, email address: *hill.shaunta@epa.gov.*

Amended Tolerances

1. *PP 2E8068.* (EPA–HQ–OPP–2012–0710). BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528, requests to amend the tolerances in 40 CFR 180.589 by removing tolerances for residues of the fungicide boscalid (BAS 510F); [3-pyridinecarboxamide, 2-chloro-*N*-(4′-chloro(1,1′-biphenyl)-2-yl)-], in or on bushberry, subgroup 13B at 13 ppm; caneberry, subgroup 13A at 6.0 ppm; canola, seed at 3.5 ppm; cotton, undelinted seed at 1.0 ppm; fruit, citrus, group 10 at 1.6 ppm; fruit, pome, group 11 at 3.0 ppm; grape at 3.5 ppm; strawberry at 4.5 ppm; sunflower, seed at 0.6 ppm; vegetable, bulb, group 3 at 3.0 ppm; vegetable, fruiting, group 8 at 1.2 ppm; and vegetable, root, subgroup 1A except sugarbeet, garden beet, radish, and turnip at 1.0 ppm, upon approval of the tolerances listed under ''New Tolerances'' for *PP 2E8068.* Contact: Andrew Ertman, (703) 308–9367, email address: *ertman.andrew@epa.gov.*

2. *PP 2E8069.* (EPA–HQ–OPP–2012–0549). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to concurrently update the existing crop group tolerances in 40 CFR 180.582 for residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate (BF 500–3); expressed as parent compound, to vegetable, bulb, group 3–07 at 0.9 ppm; vegetable, fruiting, group 8–10 at 1.4 ppm; fruit, citrus, group 10–10 at 2.0 ppm; fruit, pome, group 11–10 at 1.5 ppm; oilseed, group 20 at 0.45 ppm; caneberry subgroup 13–07A at 4.0 ppm; bushberry subgroup 13–07B at 4.0 ppm; small fruit, vine climbing subgroup (except fuzzy kiwi) 13–07F at 2.0 ppm; and low growing berry subgroup 13–07G at 1.2 ppm, upon approval of the tolerances listed under ''New Tolerances'' for *PP 2E8069.*

In addition, the IR–4 requests to concurrently amend 40 CFR 180.582 by removing tolerances for residues of pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate (BF 500–3); expressed as parent compound, in or on the raw agricultural commodity berry, group 13 at 4.0 ppm; fruit, citrus, group 10 at 2.0 ppm; fruit, pome, group 11 at 1.5 ppm; grape at 2.0 ppm; strawberry at 1.2 ppm; vegetable, bulb, group 3 at 0.9 ppm; vegetable, fruiting, group 8 at 1.4 ppm; borage, seed at 0.45 ppm; castor oil plant, seed at 0.45 ppm; Chinese tallowtree, seed at 0.45 ppm; crambe, seed at 0.45 ppm; cuphea, seed at 0.45 ppm; echium, seed at 0.45 ppm; euphorbia, seed at 0.45 ppm; evening primrose, seed at 0.45 ppm; flax seed at 0.45 ppm; gold of pleasure, seed at 0.45 ppm; Hare's ear mustard, seed at 0.45 ppm, jojoba, seed at 0.45 ppm; lesquerella, seed at 0.45 ppm, lunaria, seed at 0.45 ppm; meadowfoam, seed at 0.45 ppm; milkweed, seed at 0.45 ppm; mustard, seed at 0.45 ppm; Niger seed, seed at 0.45 ppm; oil radish, seed at 0.45 ppm; poppy, seed at 0.45 ppm; rapeseed, seed at 0.45 ppm; rose hip, seed at 0.45 ppm; safflower, seed at 0.45 ppm; sesame, seed at 0.45 ppm; stokes aster, seed at 0.45 ppm; sunflower, seed at 0.45 ppm; sweet rocket, seed at 0.45 ppm; tallowwood, seed at 0.45 ppm; tea oil plant, seed at 0.45 ppm; and ternonia, seed at 0.45 ppm, upon approval of the tolerances listed under ''New Tolerances'' for *PP 2E8069.* In plants, the method of analysis is aqueous organic solvent extraction, column clean up and quantitation by LC/MS/MS. In animals, the method of analysis involves base hydrolysis, organic extraction, column clean up and quantitation by LC/MS/MS or derivatization (methylation) followed by quantitation by GC/MS. Contact: Andrew Ertman, (703) 308–9367, email address: *ertman.andrew@epa.gov.*

3. *PP 2E8117.* (EPA–HQ–OPP–2012–0911). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to amend the tolerances in 40 CFR 180.588 for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, by removing the established tolerances in or on grape at 0.60 ppm; strawberry at 0.90 ppm; pepper, bell at 0.35 ppm; and pepper, nonbell at 1.7 ppm, upon approval of the proposed tolerances listed under ''New Tolerances'' for *PP 2E8117.* Contact: Sidney Jackson, (703) 305–7610, email address: *jackson.sidney@epa.gov.*

4. *PP 2E8118.* (EPA–HQ–OPP–2012–0912). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to amend the tolerances in 40 CFR 180.544 for residues of the insecticide methoxyfenozide, (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) including its metabolites and degradates, upon approval of the proposed tolerances listed under ''New Tolerances'' for *PP 2E8118* in paragraph (a), the petition also requests to amend the tolerances in paragraph (d)(2) from herb and spice, group 19, except coriander, leaves at 4.5 ppm to spice subgroup 19B at 4.5 ppm. In addition, it is proposed that the tolerances for residues of methoxyfenozide in or on pea, dry, seed at 2.5 ppm; bean, dry, seed at 0.24 ppm; coriander, leaves at 30 ppm; grape at 1.0 ppm; strawberry at 1.5 ppm; fruit, pome, group 11 at 1.5 ppm; vegetable, fruiting, group 8 at 2.0 ppm; and okra at 2.0 ppm be removed upon the approval of the proposed tolerances listed under ''New Tolerances'' for *PP 2E8118.* Contact: Laura Nollen, (703) 305–7390, email address: *nollen.laura@epa.gov.*

5. *PP 2F8073.* (EPA–HQ–OPP–2012–0923). Gowan Company, LLC, P.O. Box 556, Yuma, AZ 85366, requests to amend the regional restriction of tolerances in 40 CFR 180.448 for residues of the insecticide hexythiazox (trans-5-(4-chlorophenyll)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide), in or on cotton, gin byproduct at 3 ppm; and cotton, undelinted seed at 0.2 ppm by including Arizona. A practical analytical method, high pressure liquid chromatography (HPLC) with an ultraviolet (UV) detector, which detects and measures residues of hexythiazox and its metabolites as a common moiety, is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. Contact: Olga Odiott, (703) 308–9369, email address: *odiott.olga@epa.gov.*

6. *PP 2F8077.* (EPA–HQ–OPP–2012–0829). Monsanto Company, 1300 I Street NW., Suite 450 East, Washington DC 20005, (a member of the ARP), requests to delete from 40 CFR 180.470 (d) tolerances for indirect or inadvertent residues of the herbicide acetochlor (2-chloro-2'-methyl-6'-ethyl-*N*-ethoxymethyl acetanilide) and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6- methyl-aniline (HEMA) moiety, to be expressed as acetochlor equivalents, in or on beet, sugar, roots at 0.05 ppm, and beet, sugar, tops at 0.05 ppm, upon approval of the proposed tolerances listed under ''New Tolerances'' for *PP 2F8077.* Contact: Hope Johnson, (703) 305–5410, email address: *johnson.hope@epa.gov.*

7. *PP 2F8155.* (EPA–HQ–OPP–2012–0926). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419, requests to amend the tolerances in 40 CFR 180.368 for residues of the

herbicide S-metolachlor, in or on corn, field, forage; corn, sweet, forage; and corn, stover at 20, 40 and 40 ppm, respectively. A GC-nitrogen phosphorus detection (GC/NPD) method has been submitted to the Agency for determining residues in/on crop commodities and is published in PAM Vol. II, Method I. A GC/MSD method has been submitted to the Agency for determining residues in livestock commodities and is published in PAM Vol. II, Method II. These methods determine residues of S-metolachlor and its metabolites as either CGA–37913 or CGA–49751 following acid hydrolysis. Contact: Michael Walsh, (703) 308–2972, email address: *walsh.michael@epa.gov.*

New Tolerance Exemptions

1. *PP 2E8091.* (EPA–HQ–OPP–2012–0921). DuPont Tate & Lyle BioProducts, LLC, 198 Blair Bend Drive, Loudon, TN 37774, requests to establish an exemption from the requirement of a tolerance for residues of 1,3-propanediol (CAS No. 504–63–2) under 40 CFR 180.910 for pre- and post-harvest uses in pesticide formulations and 40 CFR 180.940 for food contact sanitizing solutions in public eating places, diary-processing equipment, and food-processing equipment and utensils, when used as an inert ingredient as a solvent, co-solvent, diluent, or freeze point depressant. 1,3-Propanediol would be used in or on the raw agricultural commodity and in the food contact sanitizing solution as an inert ingredient without limitation. The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. Contact: David Lieu, (703) 305–0079, email address: *lieu.david@epa.gov.*

2. *PP IN–10520.* (EPA–HQ–OPP–2012–0874). Rhodia Inc., c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192, requests to establish an exemption from the requirement of a tolerance for residues of dimethyl esters of glutaric acid (CAS No. 1119–40–0), succinic acid (CAS No. 106–65–0), and adipic acid (CAS No. 627–93–0), herein referred to as DME, under 40 CFR 180.910 when used as an inert ingredient in pesticide formulations. Rhodia is requesting that DME be exempt from the requirement of a tolerance under 40 CFR 180.910. Therefore, Rhodia believes that an analytical method to determine residues in treated crops is not relevant. Contact: Deirdre Sunderland, (703) 603–0851, email address: *sunderland.deirdre@epa.gov.*

3. *PP IN–10525.* (EPA–HQ–OPP–2012–0901). Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102, requests to establish an exemption from the requirement of a tolerance for residues of propylene glycol (CAS No. 57–55–6) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils in accordance with 40 CFR 180.940(a). The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. Contact: Mark Dow, (703) 305–5533, email address: *dow.mark@epa.gov.*

4. *PP IN–10526.* (EPA–HQ–OPP–2012–0922). Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102, requests to establish an exemption from the requirement of a tolerance for residues of sodium bisulfate (CAS No. 7681–38–1) for use as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils in accordance with 40 CFR 180.940(a). The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. Contact: David Lieu, (703) 305–0079, email address: *lieu.david@epa.gov.*

5. *PP IN–10528.* (EPA–HQ–OPP–2012–0945. Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102, requests to establish an exemption from the requirement of a tolerance for residues of FD&C Yellow No. 5 (Tartrazine) (CAS No. 1934–21–0) under 40 CFR 180.940(a) for use as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. Contact: Janet Whitehurst, (703) 305–6129, email address: *whitehurst.janet@epa.gov.*

List of Subjects in 40 CFR Part 180

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 8, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–00714 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 121210693–2693–01]

RIN 0648–BC68

Endangered and Threatened Species: Designation of a Nonessential Experimental Population of Central Valley Spring-Run Chinook Salmon Below Friant Dam in the San Joaquin River, CA

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; notice of availability.

SUMMARY: We, the National Marine Fisheries Service (NMFS), propose a rule to designate a nonessential experimental population of Central Valley spring-run Chinook salmon (*Oncorhynchus tshawytscha*) under section 10(j) of the Endangered Species Act (ESA) in portions of the San Joaquin River, and to establish take exemptions for the proposed nonessential experimental population for particular activities inside the experimental population's geographic range and outside of the current evolutionarily significant unit (ESU) designated boundary of the species in the San Joaquin River tributaries and in the Delta.

A draft environmental assessment (EA) has been prepared on this proposed action and is available for comment (see **ADDRESSES** and INSTRUCTIONS section below).

DATES: To allow us adequate time to consider your comments on this proposed rule, they must be received no later than March 4, 2013. Comments on the EA must be received by March 4, 2013. Three public meetings will be held at which the public can make comments on the draft EA and proposed rule. The first meeting will be in Chico, CA on February 5, 2013, at the Chico Masonic Family Center, 1110 West East Avenue from 5:30 p.m. to 7:30 p.m. The second meeting will be in Fresno, CA on January 24, 2013, at the Fresno Metropolitan Flood Control District, Board Meeting Room, 5469 E. Olive Avenue from 5:30 p.m. to 7:30 p.m. (The public should park in the front parking area (rear parking area closes at 5:30 p.m. with no exit after that time) and enter the door located on the west side of the front building). The third meeting

will be in Los Banos, CA on January 25, 2013 at the Los Banos Community Center, 645 7th Street from 2 p.m. to 4 p.m.

ADDRESSES: You may submit comments on this proposed rule, identified by NOAA-NMFS-2012-0221 by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA–NMFS–2012–0221, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.*
- *Mail:* Submit written comments to Elif Fehm-Sullivan, Fisheries Biologist, Protected Resources Division, Southwest Region, National Marine Fisheries Service, 650 Capitol Mall, Suite 5–100, Sacramento, California 95814.
- *Fax:* (916) 930–3629.
- *Email: SJRspring.salmon@noaa.gov.*

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

You may access a copy of the draft EA by one of the following:

- Visit NMFS' Reintroduction Web site at *http://swr.nmfs.noaa.gov/sjrrestorationprogram/salmonreintroduction.htm.*
- Call (916) 930–3723 and request to have a CD or hard copy mailed to you.
- Obtain a CD or hard copy by visiting NMFS' Central Valley office at 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814.

Please see the draft EA for additional information regarding commenting on that document.

FOR FURTHER INFORMATION CONTACT: Elif Fehm-Sullivan, National Marine Fisheries Service, 650 Capitol Mall, Suite 5–100, Sacramento, California 95814 (916–930–3723) or Dwayne Meadows, NMFS, 1315 East-West Highway, Silver Spring, MD 20910 (301–427–8403).

SUPPLEMENTARY INFORMATION:

Background Information Relevant to Experimental Population Designation

In 1988, a coalition of environmental groups, led by the Natural Resources Defense Council (NRDC), filed a lawsuit challenging renewal of long-term water service contracts between the United States and the Central Valley Project (CVP) Friant Division contractors. After more than 18 years of litigation of this lawsuit, known as *NRCD, et al.,* v. *Kirk Rodgers, et al.,* a Settlement was reached (Settlement). On September 13, 2006, the Settling Parties, including NRDC, Friant Water Users Authority (now the Friant Water Authority (FWA)), and the U.S. Departments of the Interior and Commerce, agreed on the terms and conditions of the Settlement, which was subsequently approved by the U.S. Eastern District Court of California on October 23, 2006. The Settlement establishes two primary goals: (1) Restoration Goal—To restore and maintain fish populations in ''good condition'' in the mainstem San Joaquin River below Friant Dam to its confluence with the Merced River, including naturally reproducing and self-sustaining populations of salmon and other fish, and (2) Water Management Goal—To reduce or avoid adverse water supply impacts on all of the Friant Division long-term contractors that may result from the interim and restoration flows provided for in the Settlement. Paragraph 14 of the Settlement indicates that the Restoration Goal shall include the reintroduction of Central Valley spring-run Chinook salmon (hereafter, CV spring-run Chinook salmon) to the San Joaquin River between Friant Dam and its confluence with the Merced River.

In 2009, as part of the Omnibus Public Land Management Act, Congress enacted the San Joaquin River Restoration Settlement Act (Public Law No. 111–11, 123 Stat. 1349) (SJRRSA), which ratified the terms of the litigation Settlement and provided additional authorities to the Department of the Interior to facilitate successful implementation of the Settlement. The SJRRSA provides that if the Secretary of Commerce (Secretary) concludes that a program to reintroduce CV spring-run Chinook salmon into the San Joaquin River can be implemented consistent with other requirements of the ESA, the reintroduction ''shall be [conducted] pursuant to § 10(j)'' of the ESA.

The proposed experimental population will occur in the San Joaquin River from its confluence with the Merced River upstream to Friant Dam and will include all sloughs, channels, and water ways that allow for CV spring-run Chinook salmon passage along the San Joaquin River and will also include portions of the Kings River, when high water years connect the Kings River with the San Joaquin River. While this experimental area is part of the species historical range, it is outside the current range of the CV spring-run Chinook salmon ESU.

The CV spring-run Chinook salmon ESU (70 FR 37160; June 28, 2005) is listed as threatened under the ESA, and its threatened status was recently confirmed following completion of a 5-year review (NMFS, 2011). The CV spring-run Chinook salmon ESU includes all naturally spawned populations of spring-run Chinook salmon in the Sacramento River and its tributaries, as well as the Feather River Fish Hatchery (FRFH) spring-run Chinook salmon program. We have issued protective regulations under section 4(d) of the ESA for CV spring-run Chinook salmon that prohibit their ''take'' unless otherwise authorized (50 CFR 223.203).

Statutory and Regulatory Framework for Experimental Population Designation

Section 10(j) of the ESA (16 U.S.C. 1539(j)) defines an experimental population as a population that has been authorized for release by the Secretary but only when, and at such times as, the population is wholly separate geographically from nonexperimental populations of the same species. The ESA allows the Secretary to authorize the release of ''experimental'' populations of listed species outside their current range if the release would ''further the conservation'' of the listed species. Section 10(j) also requires that before authorizing the release of an experimental population, the Secretary identify the experimental population by regulation and determine, based on the best available information, whether or not the experimental population is ''essential to the continued existence'' of the listed species (see section 10(j)(2)(B)).

The U.S. Fish and Wildlife Service (USFWS) promulgated regulations to guide its implementation of section 10(j) (see 50 CFR 17.80 through 17.84). While we do not have regulations governing the designation of experimental populations, we considered their regulations where appropriate in making the required determinations under section 10(j) and in formulating this proposed rule to designate and release an experimental population of CV spring-run Chinook salmon into the

San Joaquin River upstream of the Merced River confluence. Although the USFWS regulations do not govern our proposal, the record demonstrates that our proposal would be consistent with the criteria of those regulations. We analyzed three key elements required by Section 10(j) in formulating this proposed rule.

Element 1: In determining whether release of an experimental population of spring-run Chinook salmon into the San Joaquin River would further the conservation of the Central Valley spring-run Chinook ESU, we considered the effects of gathering broodstock on the extant populations of the ESU; the potential for the released population to survive in the foreseeable future; and the potential contribution of an experimental population to the recovery of the Central Valley spring-run Chinook ESU.

Element 2: An appropriate means to identify the experimental population, and

Element 3: Whether the experimental population is essential to the continued existence of the species in the wild or not;

In order to comply with Section 10011(c) of the San Joaquin River Restoration Settlement Act, we also considered any additional measures, appropriate to address management concerns under local conditions, and we considered a process for data collection and periodic review of the status of the experimental population.

In applying the above considerations to the proposed designation and release of the experimental population of CV spring-run Chinook salmon into the San Joaquin River, we used the best available information as required by section 10(j). We discuss in more detail below how we considered each of these three elements.

Section 10(j) of the ESA requires that an experimental population be treated as a threatened species under the ESA, with two exceptions that apply if an experimental population is not determined to be essential to the listed species' continued existence (*i.e.,* nonessential): 1) section 7 of the ESA applies in a different manner as described below in this paragraph, and 2) critical habitat shall not be designated for that experimental population. If the experimental population is determined to be nonessential, then section 10(j) requires that we apply the section 7 consultation provisions as if the population is a species proposed for listing. This means that the section 7(a)(2) consultation requirement does not apply to any experimental population of CV spring-run Chinook salmon that we determine is nonessential. The only provisions of section 7 that apply to a nonessential experimental population (NEP) are sections 7(a)(1) and 7(a)(4). Section 7(a)(1) requires that Federal agencies use their authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of threatened and endangered species. Section 7(a)(4) requires Federal agencies to confer, rather than consult, with us on actions that are likely to jeopardize the continued existence of a species proposed to be listed. The results of a conference are advisory in nature.

Section 7 of the ESA does not apply to activities undertaken on private land unless they are authorized, funded, or carried out by a Federal agency. The associated take exemptions proposed below associated with the experimental population will provide sufficient protections to reduce effects of existing or anticipated Federal or State actions, or private activities within or adjacent to the experimental population area.

Will an experimental population designation further the conservation of the species?

The ESA defines ''conservation'' as ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provide pursuant to this [Act] are no longer necessary.'' We discuss in more detail below each of the factors we considered in determining if release of an experimental population would ''further the conservation'' of CV spring-run Chinook: We first considered the most appropriate source of fish to establish an experimental population. Reintroduction efforts have the best chance for success when the donor population has life history characteristics compatible with the anticipated environmental conditions of the habitat into which fish will be reintroduced. Populations found in watersheds closest to the reintroduction area are most likely to have adaptive traits that will lead to a successful reintroduction, and therefore, only spring-run Chinook salmon populations found in the Central Valley will be used in establishing the experimental population in the San Joaquin River.

Functionally independent populations of CV spring-run Chinook salmon occur in Deer, Mill, and Butte creeks. The Feather River CV spring-run Chinook salmon population is also supplemented by operation of the FRFH. The Deer and Mill creek population levels are at a high risk of extinction and special care and consideration will be used when considering these fish as a donor source for reintroduction into the San Joaquin River. The Butte Creek CV spring-run Chinook salmon population is considered to be at a low risk of extinction and has the largest run size of the three major CV spring-run Chinook salmon populations in the Central Valley, thus it may be possible to remove fish from this population in years with high adult returns (NMFS, 2011).

Fish produced from the FRFH specifically for the reintroduction are proposed to be the initial source of individuals to establish an experimental population of CV spring-run Chinook salmon in the San Joaquin River. We would later consider diversifying the donor stock with fish from the naturally spawning population in other streams like Butte Creek if and when those populations can sustain the removal of fish. Such diversification would be subject to ESA review.

In determining whether release of the proposed experimental population would further the conservation of CV spring-run Chinook, we also considered the potential for the released population to survive in the foreseeable future. The Central Valley drainage as a whole is estimated to have supported spring-run Chinook salmon returns as large as 600,000 fish between the late 1880s and 1940s (CDFG, 1998). However, the CV spring-run Chinook salmon runs in the San Joaquin River were extirpated as a direct result of the completion of Friant Dam and the associated operation of the Friant-Kern and Madera irrigation canals which caused the river to run dry in many locations. As a result of these impacts, the last substantial CV spring-run Chinook salmon spawning cohort (numbering >1,900) returned in 1948 (Yoshiyama *et al.,* 1996). Central Valley spring-run Chinook salmon were originally most abundant in the San Joaquin River basin where the run ascended to high-elevation streams fed by snow-melt where they over-summered until the fall spawning season (Yoshiyama *et al.,* 1996). Construction of other low elevation dams in the foothills of the Sierra Nevada on the American, Mokelumne, Stanislaus, Tuolumne, and Merced rivers extirpated CV spring-run Chinook salmon in these watersheds as well (CDFG, 1998).

NMFS' Public Draft Recovery Plan for Central Valley salmonids characterizes the San Joaquin River basin below Friant Dam as having a high potential to support a spawning population of reintroduced CV spring-run Chinook salmon with implementation of the San

Joaquin River Restoration Program (SJRRP). The Settlement establishes a framework for accomplishing the Restoration Goal which includes channel and structural modifications along the San Joaquin River below Friant Dam and releases of water from Friant Dam downstream to the river's confluence with the Merced River. Based on the available information, we believe that implementation of these actions will create habitat conditions in the San Joaquin River from Friant Dam to its confluence with the Merced River sufficient to support the establishment of CV spring-run Chinook salmon populations.

In addition to actions undertaken by the SJRRP, there are many Federal and State laws and regulations that will also help ensure the establishment and survival of the experimental population by protecting aquatic and riparian habitat. Section 404 of the Clean Water Act (CWA) (40 CFR parts 100 through 149) requires avoidance, minimization, and mitigation for the potential adverse effects of dredge and fill activities within the nation's waterways. Section 404(b) of the CWA requires that section 404 permits are granted only in the absence of practicable alternatives to the proposed project, which would have a less adverse impact on the aquatic ecosystem. CWA section 401 provides protection against adverse water quality conditions. In addition, construction and operational storm water runoff is subject to restrictions under CWA Section 402 and state water quality laws. Also the Magnuson-Stevens Fishery Conservation and Management Act, as amended (16 U.S.C. 1801 *et seq.*), requires that Essential Fish Habitat (EFH) be identified and Federal action agencies must consult with NMFS on any activity which they fund, permit, or carry out that may adversely affect EFH. Freshwater EFH for Pacific salmon in the California Central Valley includes waters currently or historically accessible to salmon within the Central Valley ecosystem as described in Myers *et al.* (1998), which includes the area where this NEP is being proposed.

At the state level, the California Fish and Game Code section 1600, *et seq.* and the California Environmental Quality Act (Pub. Resources Code sections 21000 *et seq.*) (CEQA) set forth criteria for the incorporation of avoidance, minimization, and feasible mitigation measures for on-going activities as well as for individual projects. Section 1600 *et seq.* was enacted to provide conservation for the state's fish and wildlife resources and includes requirements to protect riparian habitat resources on the bed, channel, or bank of streams and other waterways. Section 1600 *et seq.* requires a person to notify the California Department of Fish and Wildlife (CDFW) (previously called California Department of Fish and Game until Dec 31, 2012) before substantially diverting or obstructing the natural flow of a river or stream. The CDFW then has the opportunity to determine whether the activity may substantially adversely affect an existing fish or wildlife resource and issue a final agreement that includes reasonable measures necessary to protect the resource (California Fish and Game Code Section 1602). Under CEQA, no public agency shall approve or carry out a project without identifying all feasible mitigation measures necessary to reduce impacts to a less than significant level, and shall incorporate such measures absent overriding considerations. In addition, protective measures, including programs for strategic screening and participation in habitat conservation programs, will be implemented in conjunction with SJRRP activities and are intended to provide a net benefit to the reintroduction.

The SJRRP restoration actions, in combination with the protective measures proposed in this rule, as well as compliance with existing Federal, State and local laws, statutes, and regulations, including those mentioned above, are expected to ensure the survivability of the experimental population in the San Joaquin River into the foreseeable future.

In addition, we considered the potential contribution of an experimental population toward recovery of the CV spring-run Chinook ESU. NMFS' draft recovery plan for Central Valley salmon and steelhead contains specific management strategies for recovering CV spring-run Chinook salmon that include securing existing populations and reintroducing populations into historically occupied habitats, including the San Joaquin River. Establishing an experimental population of CV spring-run Chinook salmon in the San Joaquin River that persist into the foreseeable future is expected to reduce the species' overall extinction risk from natural and anthropogenic factors by increasing its abundance, productivity, spatial structure, and diversity within the Central Valley. These expected improvements in the overall viability of CV spring-run Chinook salmon, in addition to other actions being implemented throughout the Central Valley, will contribute to the species recovery.

In light of the foregoing, we conclude that release of the proposed experimental population would further the conservation of CV spring-run Chinook salmon.

Identification of the Experimental Population

Section 10(j) requires that the experimental population be designated only when, and at such times, as it is geographically separate from nonexperimental populations of the same species. We are proposing to designate the experimental population area for experimental CV spring-run Chinook salmon population as the San Joaquin River from its confluence with the Merced River upstream to Friant Dam, including all sloughs, channels, and water ways that connect the San Joaquin River and provide passage for the species. In addition, the experimental area includes portions of the Kings River in high water years that provide connectivity between the Kings River with the San Joaquin River. The proposed experimental population area is within the species historical range, but it is presently unoccupied by CV spring-run Chinook salmon and is outside the currently defined freshwater and estuarine boundary of the CV spring-run Chinook salmon ESU.

False pathways (water ways that salmon follow that do not lead to spawning habitat) that fish may use as a result of restored flows have not yet been identified; however, the SJRRP includes actions to prevent or reduce straying to false pathways, and this proposed experimental population designation assumes that the SJRRP will take appropriate action to reduce losses of the experimental population caused by undesirable straying. In addition, we will be using other means of identifying fish that are part of the experimental population such as marking fish with specific fin clips or other methods (*e.g.,* coded wire tags, genetic testing).

Is the experimental population essential to the continued existence of the species?

Since we do not have regulations implementing section 10(j), we considered the USFWS regulations (50 CFR 17.80(b)), which define an essential experimental population as ''an experimental population whose loss would be likely to appreciably reduce the likelihood of the survival of the species in the wild.'' All other experimental populations are classified as nonessential. While we are not bound by the definition of ''essential'' in the USFWS regulations, we have

determined it is appropriate for use in this proposed rule.

In making the determination whether the proposed experimental population of CV spring-run Chinook salmon is essential, we used the the best available information as required by ESA section 10(j)(2)(B). Furthermore, we considered the geographic location of the proposed experimental population in relation to other populations of CV spring-run Chinook salmon, the source of fish that will be used to establish the experimental population (*e.g.,* naturally spawning populations or FRFH stocks), and whether the removal of individuals from any donor population would appreciably reduce the likelihood of the existing listed species survival and recovery in the wild.

Through our section 10 permitting authority and the section 7 consultation process, we will also ensure that the use of CV spring-run Chinook salmon from any donor populations for release into the San Joaquin River is not likely to jeopardize the continued existence of the species in the wild. Currently NMFS has issued a 10(a)(1)(A) permit along with a section 7 Biological Opinion (2012) that reached a non-jeopardy conclusion on the first five years of broodstock collection from FRFH.

As noted above, there are several choices for source populations for this experimental population. Initially we will be using FRFH fish in excess to what is needed for Feather River operations. If we consider using CV spring-run Chinook salmon from naturally spawning populations, we will remove only small numbers of fish from natural populations that we consider to be viable and at a low risk of extinction. In addition, a captive broodstock program is being established as part of the SJRRP to augment and supplement the establishment of experimental populations in the San Joaquin River. Over time, we expect the captive broodstock at the San Joaquin River conservation hatchery will produce sufficient numbers of eggs and juveniles to support reintroduction actions, and will reduce the need for fish to be taken from existing hatchery or natural populations in the Sacramento River basin.

The San Joaquin River is substantially geographically separated from the watersheds that support extant populations of CV spring-run Chinook salmon in the Sacramento River basin. We expect that any CV spring-run Chinook salmon reintroduced to the San Joaquin River will imprint on this river and would therefore be unlikely to stray into the Sacramento River basin and interact with extant populations found in that watershed. Thus it is expected that the proposed experimental population will exist as a population independent from those in the Sacramento River basin and will not contribute to their survival.

Based on these considerations, we conclude that the loss of the proposed experimental San Joaquin River population of CV spring-run Chinook salmon is not likely to appreciably reduce the likelihood of the survival of the species in the wild. Accordingly, this population will be considered nonessential under this designation.

Additional Management Restrictions, Protective Measures, and Other Special Management Considerations

The ESA defines ''take'' to mean: harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. For threatened species such as the proposed NEP of CV spring-run Chinook salmon, the ESA does not specifically prohibit take, but ESA section 4(d) (16 U.S.C. 1533(d)) provides that the Secretary shall issue protective regulations he or she deems necessary and advisable for species conservation. Such protective regulations may, if appropriate, include the take prohibitions of section 9 of the ESA.

Therefore, in conjunction with our proposal to designate and authorize the release of a CV spring-run Chinook salmon NEP in the San Joaquin River, we also propose to promulgate protective regulations under section 4(d) of the ESA that would apply to the NEP. To ensure that the NEP has protections from activities that are not lawful under Federal, State or local laws and regulations, we propose to apply all take prohibitions listed under ESA sections 9(a)(1)(A) through 9(a)(1)(G), except for section 9(a)(1)(C) which involves the irrelevant issue of take upon the high seas, to the experimental population when it is within the experimental population area. Such activities include those resulting in direct intentional take or harm or illegal activities that result in incidental take or harm. These prohibitions would apply to all CV spring-run Chinook salmon in the experimental population area that have intact adipose fins as well as those that are adipose fin-clipped.

In addition, we are proposing that the unintentional take of CV spring-run Chinook salmon in the experimental population area that is caused by otherwise lawful activities will be exempted from the take prohibitions under section 9. Similarly, this proposed rule proposes to exempt handling of fish in the experimental population for salvage/rescue and scientific research subject to specific requirements. We are proposing to provide an exemption from the section 9 take prohibitions for specified scientific research activities conducted by the State of California that is consistent with the existing state 4(d) research programs established for listed salmon, making use of the system already in place. Federal, State, and private-sponsored research activities for scientific research or enhancement purposes that are not covered under the exceptions, criteria for exceptions, and reporting requirements or exemptions provided by NMFS-approved 4(d) programs above, may take CV spring-run Chinook salmon in the NEP pursuant to the specifications of an ESA section 10 permit. Section 9(a)(1)(B) take prohibitions would not apply to ongoing research activities if an application for an ESA section 10(a)(1)(A) permit is received by NMFS, preferably through the NMFS online application Web site.

Questions regarding whether specific activities will constitute a violation of the section 9 take prohibition, and general inquiries regarding prohibitions and permits, should be directed to NMFS (see **ADDRESSES**).

As noted above, we propose to prohibit the intentional take of CV spring-run Chinook salmon in the experimental population area by angling. We intend to work with CDFW to review fishing regulations in the geographic area in order to minimize the impact of this prohibition on current angling on other species. In the future, if the experimental population becomes established, we may consider allowing limited harvest of CV spring-run Chinook salmon in the experimental population through a Fishery Management and Evaluation Plan developed by CDFW and approved by NMFS.

Special Take Exemptions Outside of the Experimental Population Area

Under the SJRRSA, the reintroduction of an experimental CV spring-run Chinook salmon population to the San Joaquin River must not impose more than *de minimis* water supply reductions, additional storage releases, or bypass flows on unwilling third parties. The SJRRSA defines ''third party'' to mean persons or entities diverting or receiving water pursuant to applicable State and Federal laws which includes CVP contractors outside of the Friant Division of the CVP and the State Water Project (SWP) contractors. Because the proposed reintroduction under the SJRRSA cannot impose any more than *de minimis* effects onto third

parties and some of these third parties operate outside of the proposed experimental population area, this proposed rule also extends special take exemptions to third parties outside of the experimental population area geographic location. These proposed special take exemptions will apply to fish that originate from the San Joaquin River, including the experimental area above the confluence with the Merced River. Spring-run Chinook salmon that are part of the threatened CV spring-run Chinook salmon ESU (50 CFR 223.102), and are known to occur in the area, will be exempt from take prohibitions for activities related to diverting or receiving water pursuant to applicable State and Federal laws, but otherwise would continue to be covered by the take prohibitions applicable to the non-experimental part of the ESU. The proposed special take exemptions for CV spring-run Chinook salmon that originate from the San Joaquin River would address areas downstream from the confluence of the Merced and San Joaquin rivers, including all tributaries to the San Joaquin River and in the south Delta.

For take at the CVP and SWP facilities in the Delta, NMFS will annually calculate and document the proportionate contribution of CV spring-run Chinook salmon originating from the reintroduction to the San Joaquin River. NMFS will document this calculation by January 15 each year and will describe the method for calculating and deducting this share of CV spring-run Chinook salmon take from the operational triggers and incidental take statements associated with the June 2009 Biological Opinion on the Long-term Operations of the CVP and SWP or subsequent future Biological Opinions. The intent of this proposed exemption is to ensure that the proposed experimental reintroduction will not impose more than a *de minimis* impact on water supply, storage releases and bypass flows for unwilling third parties due to the reintroduction.

Process for Periodic Review

Monitoring and analysis is necessary to gauge the progress of the proposed reintroduction program and to provide information for decision-making and adaptive management. Fish passage, fish biology, aquatic habitat, and conservation hatchery facility operations will be the primary focus of the monitoring (FMP, 2009).

Fish passage monitoring will focus on addressing a variety of issues important to successful reintroduction. These issues consist of measuring fish passage efficiency, smolt injury and mortality rates, and adult river passage to spawning areas. Passive integrated transponder tags and radio tags will be used to evaluate and monitor fish passage effectiveness. Biological evaluation and monitoring will concentrate on adult escapement and spawning success, competition with resident species, predation, disease transfer, smolt production, harvest, and sustainability of natural runs. Habitat monitoring will focus on long-term trends in the productive capacity of the reintroduction area (*i.e.,* habitat availability, habitat effectiveness, riparian condition) and natural production (the number, size, productivity, and life history diversity) of CV spring-run Chinook salmon in the experimental population area.

Monitoring at the conservation hatchery facility will focus on multiple issues important to the quality of fish collected and produced for use in the reintroduction program. CDFW will be primarily responsible for monitoring conservation hatchery facility operations. Monitoring activities will consist mainly of tracking broodstock sources; disease history and treatment; pre-release performance such as survival, growth, and fish health by life stage; the numerical production advantage provided by the conservation hatchery facility program relative to natural production; and success of the conservation hatchery facility program in meeting the programs objectives.

While this monitoring is being conducted for purposes of making the reintroduction effort successful, we will use the information to also determine if the experimental population designation is causing any harm to CV spring-run Chinook salmon that are part of the threatened ESU and their habitat, and then, based on this and other available information, determine if any changes to the experimental population designation may be warranted. Any contribution that an experimental population might make to the overall viability of CV spring-run Chinook salmon would be considered in future status assessments required under the ESA.

Experimental Population Findings

Based on the best available scientific information, we have determined that the designation and release of a NEP of CV spring-run Chinook salmon in the San Joaquin River basin below Friant Dam will further the conservation of CV spring-run Chinook salmon. Fish used for the reintroduction will rely on FRFH hatchery production or fish produced from a conservation hatchery facility from limited collection of wild fish, and loss of some fish will not reduce the survival and recovery of CV spring-run Chinook salmon. The collection of wild fish will be permitted only after issuance of permits under section 10(a)(1)(A) of the ESA that ensure that any such collections will not jeopardize the survival and recovery of the species. We have determined that this experimental population is nonessential because it is not necessary for the continued survival of the CV spring-run Chinook salmon; however, the population is expected to contribute to the recovery of CV spring-run Chinook salmon if the reintroduction is successful. This experimental population designation and release is being implemented in association with the reintroduction efforts called for in the SJRRP and the Stipulation of Settlement. Actions of the SJRRP are intended to provide habitat conditions that will be sufficient to establish a CV spring-run Chinook salmon population in the San Joaquin River while at the same time ensuring that no further protections will be needed and that the reintroduction will not impact landowners and third parties as defined by the SJRRSA.

The success of the reintroduction of CV spring-run Chinook salmon in the experimental population area will be monitored as part of the SJRRP. We will assess the contribution of the NEP to the status of the species during the required five year status review of the CV spring-run Chinook salmon ESU. This information will be used by NMFS to determine if changes to the NEP designation may be warranted.

As previously noted, we considered the Fish and Wildlife Service's regulations and applied them only where appropriate in this proposed rule. We believe that our identification of the proposed experimental population, our finding that release of the proposed experimental population would further the conservation of CV spring-run Chinook, and our finding that the proposed experimental population is not essential to the continued existence of the listed species would be identical had we strictly applied all of the Fish and Wildlife Service's 10(j) regulations.

Public Comment

We want the final rule to be as effective and accurate as possible, and the final EA to evaluate the potential issues and reasonable range of alternatives. Therefore, we invite the public, State, Tribal, and government agencies, the scientific community, environmental groups, industry, local landowners, and all interested parties to provide comments on the proposed rule

and EA. We request that submitted comments be relevant to the reintroduction and experimental population designation and not include comments on the SJRRP as a whole, which is beyond the scope of the action described in this proposed rule. Comments should be as specific as possible, provide relevant information or suggested changes, the basis for the suggested changes, and any additional supporting information where appropriate. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Prior to issuing a final rule, we will take into consideration the comments and supporting materials received. The final rule may differ from the proposed rule based on this information and other considerations. We are interested in all public comments, but are specifically interested in obtaining feedback on:

(1) The geographical boundary of the designated experimental population.

(2) The extent to which the experimental population would be affected by current or future Federal, State, or private actions within or adjacent to the experimental population area.

(3) Any necessary management restrictions, protective measures, or other management measures that we may have not considered.

(4) The extent to which we have has provided protections for third parties as required by the SJRRSA.

(5) Whether we should propose the experimental population as nonessential.

(6) Whether the proposed designation furthers the conservation of the species and we have used the best available science in making this determination.

Information Quality Act and Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review pursuant to the Information Quality Act (Section 515 of Pub. L. 106–554) in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. The peer review requirements of the OMB Bulletin apply to influential or highly influential scientific information disseminated on or after June 16, 2005. There are no documents supporting this proposed rule that meet this criteria.

Classification

Executive Order 12866

This rule has been determined to be not significant under E.O. 12866.

Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*):

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 801 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

We are certifying that this rule would not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale. The effect of the proposal would be to avoid the need for affected entities, including small entities, to obtain ESA permits or authorization to conduct otherwise lawful activities as a result of reintroduction of CV spring-run Chinook salmon to the San Joaquin River. We do not collect the data to be able to quantify the number or type of small entities within the area affected by this proposed rule. If this proposal is adopted, the area affected by this rule includes the San Joaquin River from Friant Dam to Mossdale County Park, San Joaquin County, California and associated water ways accessible to anadromous fish. The NEP area would include the San Joaquin River from Friant Dam downstream to the confluence with the Merced River. Private land ownership is significant in the NEP area. Land uses are primarily agriculture, recreation, and tourism.

This proposed rule authorizes incidental take of CV spring-run Chinook salmon within the NEP area. The regulations implementing the ESA define ''incidental take'' as take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Intentional take for negligent, or as a result of unlawful, activities would not be permitted. Intentional take other than for conservation purposes as described in the special rule are not authorized unless for research or educational purposes, which would require a section 10 permit under the ESA. Because of the substantial regulatory relief provided by NEP designations, we do not expect this rule to have any significant effect on recreational, agricultural, or development activities within the NEP area.

Additionally, the proposal would provide specific regulatory relief to persons or entities diverting or receiving water pursuant to applicable State and Federal laws, such that the reintroduction of CV spring-run Chinook salmon would not impose more than *de minimus:* Water supply reductions, additional storage releases, or bypass flows on these persons or entities, if unwilling. These exemptions include Central Valley Project contractors outside of the Friant Division of the Central Valley Project and the State Water Project. Because this proposal would require no additional regulatory requirements on small entities and would provide regulatory relief for activities within the affected area, the Chief Council for Regulation certified that this proposed rule would not have a significant economic effect on a substantial number of small entities.

Executive Order 12630

In accordance with E.O. 12630, the proposed rule does not have significant takings implications. A takings implication assessment is not required because this proposed rule: (1) Would not effectively compel a property owner to have the government physically invade their property, and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This proposed rule would substantially advance a legitimate government interest (conservation and recovery of a listed fish species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Executive Order 13132

In accordance with E.O. 13132, we have determined that this proposed rule does not have federalism implications as that termed is defined in E.O. 31312.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. This proposed rule does not include any new collections of information that require approval by OMB under the Paperwork Reduction Act.

National Environmental Policy Act

In compliance with all provisions of the National Environmental Policy Act of 1969 (NEPA), we have analyzed the impact on the human environment and considered a reasonable range of alternatives for this proposed rule. We have prepared a draft EA on this proposed action and have made it available for public inspection (see **ADDRESSES** section). All appropriate NEPA documents will be finalized before this rule is finalized.

Government-to-Government Relationship With Tribes (E.O. 13175)

E.O. 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests. If we issue a regulation with tribal implications (defined as having a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes) we must consult with those governments or the Federal Government must provide funds necessary to pay direct compliance costs incurred by tribal governments.

There are no tribally owned or managed lands included in the experimental population area. We have invited all possibly impacted tribes (letter dated November, 15, 2010, from Maria Rea, Central Valley Office Supervisor, NMFS) to discuss the proposed rule at their convenience should they choose to have a government-to-government consultation.

References Cited

A complete list of all references cited in this proposed rule is available upon request from National Marine Fisheries Service office (see **FOR FURTHER INFORMATION CONTACT**).

Dated: January 9, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

List of Subjects in 50 CFR Part 223

Endangered and threatened species, Exports, Imports.

For the reasons set out in the preamble, we propose to amend part 223, subpart B of chapter 1, title 50 of the Code of Federal Regulations, as set forth below.

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. Add § 223.301 paragraph (b) to read as follows:

§ 223.301 Special rules—marine and anadromous fishes.

* * * * *

(b) San Joaquin River CV spring-run Chinook Salmon Experimental Population (*Oncorhynchus tshawytscha*).

(1) The San Joaquin River CV spring-run Chinook salmon population identified in paragraph (b)(5) of this section is designated as a nonessential experimental population under section 10(j) of the ESA.

(2) *Prohibitions.* The prohibitions of section 9(a)(1) of the ESA (16 U.S.C. 1538 (a)(1)) relating to endangered species apply to fish that are part of the threatened, nonessential experimental population of CV spring-run Chinook salmon identified in paragraph (a)(4) of this section.

(3) *Allowable take of CV spring-run Chinook salmon in the Experimental Population Area:*

(i) Any taking of CV spring-run Chinook salmon provided that it is unintentional, not due to negligent conduct, and incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Examples of otherwise lawful activities include recreation, agriculture, municipal usage, and other similar activities, which are carried out in accordance with Federal, State, and local laws and regulations.

(ii) Any taking of CV spring-run Chinook salmon by an employee or designee of NMFS, the USFWS, other Federal land management agencies, the California Department of Fish and Wildlife, or any other governmental entity if in the course of their duties it is necessary to: aid a sick, injured or stranded fish; dispose of a dead fish; or salvage a dead fish which may be useful for scientific study. Any agency acting under this provision must report to NMFS (see **ADDRESSES** section) the numbers of fish handled and their status on an annual basis.

(iii) Any taking of CV spring-run Chinook salmon for scientific research or enhancement purposes by a person or entity with a valid section 10(a)(1)(A) permit issued by NMFS and a valid permit issued by the CDFW.

(iv) Any taking of CV spring-run Chinook salmon for scientific research purposes by the CDFW provided that:

(A) Scientific research activities involving purposeful take are conducted by employees or contractors of CDFW or as a part of a monitoring and research program overseen by or coordinated with CDFW.

(B) CDFW provides for NMFS' review and approval a list of all scientific research activities involving direct take planned for the coming year, including an estimate of the total direct take that is anticipated, a description of the study design, including a justification for taking the species and a description of the techniques to be used, and a point of contact.

(C) CDFW annually provides to NMFS the results of scientific research activities directed at fish in the experimental population, including a report of the direct take resulting from the studies and a summary of the results of such studies.

(D) Scientific research activities that may incidentally take fish in the experimental population are either conducted by CDFW personnel, or are in accord with a permit issued by the CDFW.

(E) CDFW provides NMFS annually, for its review and approval, a report listing all scientific research activities it conducts or permits that may incidentally take fish in the experimental population during the coming year. Such reports shall also contain the amount of incidental take occurring in the previous year's scientific research activities and a summary of the results of such research.

(F) Electro fishing in any body of water known or suspected to contain fish in the experimental population is conducted in accordance with NMFS ''Guidelines for Electrofishing Waters Containing Salmonids Listed Under the Endangered Species Act'' (NMFS, 2000a).

(G) NMFS' approval of a research program shall be a written approval by NMFS Northwest or Southwest Regional Administrator.

(4) *Take of CV spring-run Chinook salmon in Experimental Population Area that is not allowed:*

(i) Except as expressly allowed in paragraph (3) of this section, the taking of CV spring-run Chinook salmon is prohibited within the experimental population area. This includes the taking of CV spring-run Chinook salmon by all activities that are illegal or not allowed under Federal, State or local laws and regulations.

(ii) No person shall possess, sell, deliver, carry, transport, ship, import, or export, by any means whatsoever, CV spring-run Chinook salmon from the nonessential, experimental population area in violation of this paragraph and paragraph (2) of this section.

(5) *San Joaquin River CV Spring-run Chinook Salmon Experimental Population Area.*

The geographic boundary defining the experimental population of CV spring-run Chinook salmon includes the San Joaquin River from Friant Dam downstream to its confluence with the Merced River as well as all sloughs, channels, and waterways connected with the San Joaquin River that allow for CV spring-run Chinook salmon passage. Those portions of the Kings River that connect with the San Joaquin River during high water years are also part of the experimental population area. The experimental population area is within the historic range of the species, but is outside of its current range. All CV spring-run Chinook salmon in this defined experimental population area are considered part of the San Joaquin River experimental population.

(6) *Special Take Exemption Outside of the Experimental Population Area:*

(i) Any taking of CV spring-run Chinook salmon in those portions of the lower San Joaquin River and its tributaries downstream from its confluence with the Merced River to Mossdale County Park in San Joaquin County, by otherwise lawful activities related to diverting or receiving water pursuant to applicable State and Federal laws.

(ii) Any taking of CV spring-run Chinook salmon at the CVP and SWP projects in the Delta that originates from reintroduction to the San Joaquin River. NMFS will annually determine by January 15 the share of take at the CVP and SWP facilities that originates from the reintroduction to the San Joaquin River. This determination will provide a methodology for deducting San Joaquin River origin spring-run Chinook salmon from the operational triggers and incidental statements associated with any biological opinion that is in effect at the time for operations of the CVP and SWP facilities.

[FR Doc. 2013–00809 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 78, No. 11

Wednesday, January 16, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—FNS–380, Worksheet for the Supplemental Nutrition Assistance Program Quality Control Reviews

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection of FNS–380, Worksheet for the Supplemental Nutrition Assistance Program's Quality Control Reviews.

DATES: Written comments must be received on or before March 18, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Francis B. Heil, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 822, Alexandria, VA 22302. Comments may also be submitted via email to *SNAPHQ-Web@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Francis B. Heil at 703–305–2442.

SUPPLEMENTARY INFORMATION:

Title: Worksheet for the Supplemental Nutrition Assistance Program's (SNAP) Quality Control Reviews.

Form Number: FNS–380.

OMB Number: 0584–0074.

Expiration Date: April 30, 2013.

Type of Request: Revision of a currently approved collection.

Abstract: Form FNS–380, is a SNAP worksheet used to determine eligibility and benefits for households selected for review in the quality control sample of active cases. We estimate the total reporting burden for this collection of information as 8.9 hours, equating to a total of 467,631 hours collectively. This includes the time for State agencies analyzing the household case record; planning and carrying out the field investigation; gathering, comparing, analyzing and evaluating the review data and forwarding selected cases to the Food and Nutrition Service for Federal validation. It also includes an average interview burden of 30 minutes (0.5 hours) for each household. Additionally, we estimate the recordkeeping burden per record for the State agency to be 0.0236 hours, thereby making the recordkeeping burden associated with this information collection for the State agency to be 1,226 hours. The total estimated reporting and recordkeeping burden for this collection is 463,661.33 hours.

The reporting and recordkeeping burden for this form was previously approved under OMB clearance number 0584–0074. OMB approved the burden through April 30, 2013. Based on the most recent table of active case sample sizes and completion rates (FY2011), we estimate 51,959 FNS–380 worksheets and interviews will now be completed annually. This is a decrease of 4,106 responses from the estimate made to substantiate the current collection. This estimate will also cause a corresponding decrease in the reporting and recordkeeping burden. The decrease in response is a result of a reduction in the number of cases being pulled for review over the minimum required review amount. We are requesting a three-year approval from OMB for this information collection.

Affected Reporting Public: State, Local and Tribal Governments.

Estimated Number of Respondents: 53 State Agencies (SA).

Estimated Number of Responses per Respondent: 980.3584906.

Estimated Total Annual Responses: 51,959.

Estimated Time per Response: 8.4 hours per.

Estimated Total Burden for SA: 436,455.6.

Affected Reporting Public: Households (HH).

Estimated Number of Respondents: 51,959.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 51,959.

Estimated Time per Response: .5 hours.

Estimated Total Burden for HH: 25,979.5.

Overall Total Reporting burden: 462,435.10 hours.

Affected Recordkeeping Public: State, Local and Tribal Governments.

Estimated Number of Respondents: 53 State Agencies.

Estimated Number of Responses per Respondent: 980.3584906.

Estimated Total Annual Responses: 51,959.

Estimated Time per Response: 0.0236 hours.

Overall Total Recordkeeping burden: 1,226.2324 hours.

Estimated Total Annual Burden on Respondents: 463,661.33 hours.

Respondent	Estimated number of respondents	Responses annually per respondent	Total annual responses (col. b × c)	Estimated avg. number of hours per response	Estimated total hours (col. d × e)
Reporting Burden					
STATE AGENCIES	53	980.3584906	51,959	8.4	436,455.6
HOUSEHOLDS	51,959	1	51,959	.5	25,979.5
Total Reporting Burden	52,012		103,918		462,435.10
Recordkeeping Burden					
STATE AGENCIES	53	980.3584906	51,959	0.0236	1,226.2324
Total Recordkeeping Burden	53		51,959		1,226.2324
Total Overall Burden Hours	52,012	3.00	155,877	2.97	463,661.33

Dated: January 10, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–00812 Filed 1–15–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection: Comment Request: FNS–583, Supplemental Nutrition Assistance Program Employment and Training Program Activity Report

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act, this notice invites the public and other public agencies to comment on a proposed information collection burden for the Supplemental Nutrition Assistance Program (SNAP), Employment and Training (E&T) Program, currently approved under OMB No. 0584–0339. This is a revision of a currently approved collection, which proposes to decrease the currently approved burden of 26,083 hours by 4,194. The adjusted burden is 21,889 hours. This decrease is due to greater efficiencies in tracking and reporting E&T component placements. In prior collections, FNS estimated that State agencies used one minute per component placement to compile and record this data. This estimate is now reduced to 10 seconds per component placement, which is the same amount of time allotted for States to compile and record work registrant data.

DATES: Submit written comments on or before March 18, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed collection of information, including validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other form of information technology.

Comments may be sent to Moira Johnston, Chief, Program Design Branch, Program Development Division, Supplemental Nutrition Assistance Program, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 810, Alexandria, Virginia 22302. Comments may also be submitted via fax to the attention of Moira Johnston at 703–305–2454 or via email to *moira.johnston@fns.usda.gov.*

Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically. All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia 22302, Room 810.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of this information collection should be directed to Moira Johnston at (703) 305–2515.

SUPPLEMENTARY INFORMATION:

Title: Employment and Training Program Activity Report.

OMB Number: 0584–0339.

Expiration Date: April 30, 2013

Type of Request: Revision of a currently approved collection.

Abstract: 7 CFR 273.7(c)(9) requires State agencies to submit quarterly E&T Program Activity Reports containing monthly figures for participation in the program. FNS uses Form FNS–583, to collect participation data. The information collected on the FNS–583 report includes:

- On the first quarter report, the number of work registrants receiving SNAP as of October 1 of the new fiscal year;
- On each quarterly report, by month, the number of new work registrants; the number of able–bodied adults without dependents (ABAWDs) applicants and recipients participating in qualifying components; the number of all other applicants and recipients (including ABAWDs involved in non-qualifying activities) participating in components; and the number of ABAWDs exempt under the State agency's 15 percent exemption allowance;
- On the fourth quarter report, the total number of individuals who participated in each component, which is also sorted by ABAWD and non-ABAWD participants and the number of individuals who participated in the E&T Program during the fiscal year.

7 CFR 273.7(d)(1)(i)(D) provides that if a State agency will not expend all of the funds allocated to it for a fiscal year, FNS will reallocate unexpended funds to other State agencies during the fiscal year or the subsequent fiscal year as FNS considers appropriate and

equitable. After FNS makes initial E&T allocations, State agencies may request more funds as needed. Typically FNS receives fourteen such requests per year.

The time it takes to prepare these requests is included in the burden. After receiving the State requests, FNS will reallocate unexpended funds as provided above. Following is the revised estimated burden for E&T reporting including the burden for State agencies to request additional funds.

Reporting

FNS–583 Report

Frequency: 4.
Affected Public: State Agency.
Number of Respondents: 53.
Number of Responses: 684. (Note this reflects multiple responses within the FNS–583 form; In aggregate, 53 State Agencies submit 1 form each quarter or 212 total responses per year.)
Estimated Time per Response: 31.9363 hours per State agency.
Estimated Total Annual Reporting Burden: 21,844.40 hours.

Requests for Additional Funds

Frequency: .2641
Affected Public: State Agency.
Number of Respondents: 53.
Number of Responses: 14.
Estimated Time per Response: 1.00 hour per request.
Estimated Total Annual Reporting Burden: 14 hours.

Recordkeeping

FNS–583 Report

Number of Respondents: 53.
Number of Records: 212.
Number of Hours per Record: 0.137 hours.
Estimated Total Annual Recordkeeping Burden: 29.04 hours.

Requests for Additional Funds

Number of Respondents: 53.
Number of Records: 14.
Number of Hours per Record: 0.137 hours.
Estimated Total Annual Recordkeeping Burden: 1.92 hours.

TOTAL ANNUAL REPORTING AND RECORDKEEPING BURDEN

[Compiling and reporting for the FNS–583 and requests for more funding]
[Snap employment and training program activity report]

Section of regulation	Title	Number of respondents	Reports filed annually	Total responses (C × D)	Estimated number of hours per response	Estimated total hours (C × D × F)
A	B	C	D	E	F	G
REPORTING						
7 CFR 273.7(c)(8)	Compile and report new work registrants on FNS–583.	53	4	212	90.94	19,278.28
7 CFR 273.24(g)	Compile and report 15 percent ABAWD exemptions on FNS–583.	* 12	4	48	4.59	220.32
7 CFR 273.7(f)	Compile and report E&T activities (placements) on FNS–583.	53	4	212	10.10	2,142.20
7 CFR 273.7(C)(8)	Preparing FNS–583:.					
	States filing electronically	50	4	200	1.00	200
	States filing manually	3	4	12	0.3	3.6
7 CFR 273.7(d)(1)(i)(F)	Preparing requests for more funds after initial allocation.	53	0.2641	14	1	14
Total Reporting for FNS–583 and Additional Funds Requests.		53	13.1698	698	31.32	21,858.40
RECORDKEEPING						
7 CFR 277.12	Recordkeeping burden for FNS–583.	53	4	212	0.137	29.04
7 CFR 277.12	Record-keeping burden for additional requests.	53	0.26415	14	0.137	1.92
Total Recordkeeping Burden for FNS 583 and Additional Funds Requests.		53	4.26	226	0.137	30.96
SUMMARY						
Total All Burdens		53	17.43	924	23.689	21,889.36

* There are 12 States without statewide waivers of the time-limit that will likely use 15 percent exemptions in FY2013.

Dated: January 10, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–00815 Filed 1–15–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Senior Farmers' Market Nutrition Program (SFMNP)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a renewal of the currently approved collection for the Senior Farmers' Market Nutrition Program (SFMNP).

DATES: Written comments must be received on or before March 18, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Donna Hines, Chief, Policy Branch, Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 528, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Donna Hines at 703–305–2196 or via email to *wichq-web@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Donna Hines, Chief, Policy Branch, Supplemental Food Programs Division at 703–305–2746 or *Donna.Hines@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Senior Farmers' Market Nutrition Program (SFMNP).

Form Number: FNS 683A.

OMB Number: 0584–0541.

Expiration Date: March 3, 2013.

Type of Request: Renewal of a currently approved collection.

Abstract: Section 4231 of the Food, Conservation and Energy Act of 2008 (Pub. L. 110–246, also known as the Farm Bill) reauthorized the Senior Farmers' Market Nutrition Program (SFMNP) through fiscal year 2012; a prior law (the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171)) gave the Department of Agriculture the authority to promulgate regulations for the operation and administration of the SFMNP. These regulations are published at 7 CFR Part 249. The purposes of the SFMNP are to provide resources in the form of fresh, nutritious, unprepared, locally grown fruits, vegetables, honey and herbs from farmers' markets, roadside stands, and community supported agriculture (CSA) programs to low income seniors; to increase the domestic consumption of agricultural commodities by expanding or aiding in the expansion of domestic farmers' markets, roadside stands, and CSA programs; and to develop or aid in the development of new and additional farmers' markets, roadside stands, and CSA programs.

USDA published a final rulemaking on the SFMNP on December 6, 2006 (71 FR 74618), that contained an estimated information collection burden based on the rule's requirements for program operation and administration. The previous SFMNP information collection burden was approved by the Office of Management and Budget (OMB) for 3 years, effective March 2010, under RIN 0584–0541. The Department is now soliciting comments on the accuracy and reasonableness of the renewal of this estimated burden.

The estimated total annual Reporting and Recordkeeping burden is 465,319 hours. The estimated total burden is 32,459 hours lower than the previously approved collection burden. Several SFMNP State agencies reported a decrease in the number of participants served and number of authorized farmers' markets. See the table below for estimated total annual burden for each type of respondent.

Reporting Burden

Affected Public: Respondents include State agencies, local agencies, individuals/households (participants), and authorized SFMNP farms (farmers, farmers' markets, roadside stands, and CSA programs).

Estimated Number of Respondents: The total estimated number of respondents is 906,196. This includes: State agencies, local agencies, individuals/households (participants), and authorized SFMNP farms (farmers, farmers' markets, roadside stands, and CSA programs).

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 906, 196.

Estimated Time per Response: .263 hours.

Estimated Total Annual Burden on Respondents: 237,922 hours.

Recordkeeping Burden

Estimated Number of Recordkeepers: 900,255.

Respondents include: State and local agencies.

Estimated Number of Records per Respondent: 1.

Estimated Time per Recordkeeping: .253 hours.

Estimated Total Annual Burden on Respondents: 227,397.

Estimated Total Annual Reporting/Recordkeeping Requirements: 465,319 hours.

Regulation section	Title	Estimated number of respondents	Reports filed annually	Total annual response	Estimated hours/ response	Annual burden hours
Affected Public: STATE & LOCAL AGENCIES (Including Indian Tribal Organizations and US Territories)						
Reporting						
249.3(e)	Local Agency Applications	510	1	510	2	1,020
249.4	State Plan	51	1	51	40	2,040
249.10(e)	Monitoring/review of outlets	804	1	804	1.5	1,206
249.10(f)	Coupon/CSA management system.	51	1	51	5	255
249.10(h)	Coupon reconciliation	51	1	51	3	153
249.11	Financial management system.	51	1	51	10	510
249.12	Prior Approval for costs per 7 CFR 3016.22.	5	1	5	160	800
249.17(b)(2)	State agency corrective action plans.	12	1	12	10	120
249.18(b)	Audit responses	12	1	12	15	180
249.23(b)	Financial/recipient reports	51	1	51	40	2,040
Subtotal	(Reporting Requirements)	1,598		1,598	5.20	8,324
Affected Public: INDIVIDUALS/HOUSEHOLDS (Applicants for Program Benefits)						
Reporting						
249.6 (a)(3)	Certification data for seniors.	900,000	1	900,000	0.25	225,000
Subtotal	(Reporting Requirements)	900,000		900,000		225,000
Affected Public: Farms (Farmers/Markets/Roadside stands/CSA's)						
Reporting						
249.10(b)	Farmer applications & agreements.	4,598	1	4,598	1	4,598
Subtotal	(Reporting Requirements)	4,598		4,598		4,598
Subtotal Reporting		906,196	1	906,196	.263	237,922
Affected Public: STATE & LOCAL AGENCIES (Including Indian Tribal Organizations and US Territories)						
Recordkeeping						
249.9	Nutrition education	900,000	1	900,000	0.25	225,000
249.10(b)	Authorized outlet agreements.	51	1	51	2	102
249.10(e)	Summary of authorized outlet monitoring.	51	1	51	2	102
249.11	Record of financial expenditures.	51	1	51	2	102
249.16(a)	Fair hearings	51	1	51	1	51
249.23(a)	Record of program operations.	51	1	51	40	2,040
Subtotal	(Recordkeeping Requirements).	900,255	1	900,255	.253	227,397
Total Burden	(Reporting & Recordkeeping).	1,806,451		1,806,451		465,319

Dated: January 10, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–00816 Filed 1–15–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Performance Reporting System, Management Evaluation

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection under OMB 0584–0010, which is due to expire April 30, 2013.

DATES: Written comments must be received on or before March 18, 2013.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments may be sent to: Billy DeLancey, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 8–44, Alexandria, VA 22302.

Comments may also be submitted via fax to the attention of Billy DeLancey at 703–305–2486 or via email to *Billy.DeLancey@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Billy DeLancey at 703–305–2480.

SUPPLEMENTARY INFORMATION:

Title: Performance Reporting System, Management Evaluation.

OMB Number: 0584–0010.

Expiration Date: 4/30/2013.

Type of Request: Revision of a currently approved collection.

Abstract: The purpose of the Performance Reporting System (PRS) is to ensure that each State agency and project area is operating the Supplemental Nutrition Assistance Program (SNAP) in accordance with the requirements of the Food and Nutrition Act of 2008 (the Act) (7 U.S.C. 2011, *et seq.*), as amended and corresponding program regulations. Under Section 11 of the Act (7 U.S.C. 2020), State agencies must maintain necessary records to ascertain that SNAP is operating in compliance with the Act and regulations and must make these records available to the Food and Nutrition Service (FNS) for inspection and audit.

Management Evaluation (ME) Review Schedules—Unless the State receives approval for an alternative Management Evaluation review schedule, each State agency is required, under 7 CFR part 275, to submit one review schedule every one, two or three years, depending on the project area make-up of the State.

Data Analysis—Under 7 CFR part 275, each State must establish a system for analysis and evaluation of all data available to the State. Data analysis and evaluation is an ongoing process that facilitates the development of effective and prompt corrective action.

Corrective Action Plans—Under 7 CFR part 275, State agencies must prepare a corrective action plan (CAP) addressing identified deficiencies. The State agencies must develop a system for monitoring and evaluating corrective action and submit CAP updates, as necessary.

Affected Public: SNAP State and local agencies.

Estimated Number of Respondents: 53 State agencies.

Estimated Number of Responses per Respondent: (1) State agencies will submit one review schedule and one ME review plan per year, and will conduct and document ME reviews for an average total of 28.98 responses each.

Estimated Total Annual Responses: 1,536 (53 review schedules + 53 review plan development + 1,430 project areas)

Estimated Time per Response: FNS estimates that it takes 4 hours to prepare a review schedule, and that each of the 53 State agencies will submit one review schedule per year resulting in a total burden of 212 hours. FNS estimates that it takes on average approximately 80 hours to develop a comprehensive State review plan, resulting in a total of 4,240 hours.

FNS estimates that it takes an average of 340 hours to conduct a review. It is estimated that ME reviews are conducted for one-half of the total number of project areas (1,430).

Therefore, FNS estimates that it takes approximately 486,200 hours annually for State agencies to conduct their reviews.

FNS also estimates that the time necessary for record keeping, that is, the time necessary to find and file a record in the conduct of an ME review is .1169 hours per State agency. Therefore, the total amount of time for recordkeeping is 180 hours.

Estimated Total Annual Reporting and Recordkeeping Burden: 490,832 hours

Respondent	Estimated number of respondents	Responses annually per respondent/ reviews	Total annual responses (col. b × c)	Estimated average number of hours per response	Estimated total hours (col. d × e)
Reporting Burden					
State and local agencies review schedule	53	1	53	4	212
State and Local review plan development	53	1	53	80	4,240
State and Local agencies conducting reviews	53	26.98	1,429.94	340	486,179.60
Total Reporting Burden	53		1,536		490,631.6
Recordkeeping Burden					
State and local agencies	53	28.98	1,536	.1169	179.56
Total Recordkeeping Burden	53		1,536		180

Dated: January 10, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–00823 Filed 1–15–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2010–2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 10, 2012, the Department of Commerce (''Department'') published the preliminary results of, and intent to rescind in part, the 2010–2011 administrative review of the antidumping duty order on tapered roller bearings (''TRBs'') from the People's Republic of China (''PRC'').[1] Further, the Department released the results of its post-preliminary analysis on December 7, 2012.[2] The period of review (''POR'') is June 1, 2010, through May 31, 2011.

This review covers five respondents: (1) Changshan Peer Bearing Company, Ltd. (''CPZ/SKF''); (2) Xiang Yang Automobile Bearing Co., Ltd. (''ZXY''); (3) Tianshui Hailin Import and Export Corporation (''Tianshui Hailin''); (4) Haining Automann Parts Co., Ltd. (''Haining Automann''); and (5) Zhejiang Zhaofeng Mechanical and Electronic Co., Ltd. (''Zhejiang Zhaofeng'').

We invited interested parties to comment on our *Preliminary Results* and post-preliminary analysis. Based on our analysis of the comments received, we made certain changes to our margin calculations for CPZ/SKF. The final weighted-average dumping margins for this review are listed in the ''Final Results of Review'' section below.

DATES: *Effective Date:* January 16, 2013.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander or Erin Kearney, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0182 or (202) 482–0167, respectively.

Background

On July 10, 2012, the Department published its *Preliminary Results* in the antidumping duty administrative review of TRBs from the PRC. The Timken Company (''Petitioner'') submitted post-preliminary surrogate value data on July 30, 2012. Petitioner and CPZ/SKF each submitted case briefs on August 9, 2012, and rebuttal briefs on August 14, 2012. On October 17, 2012, the Department extended the deadline for the final results by 60 days, until January 6, 2013. On October 31, 2012, as explained in the memorandum from the Assistant Secretary for Import Administration, the Department exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 29, through October 30, 2012, which extended the deadline for the final results by two additional days, until January 8, 2013.[3] On December 7, 2012, the Department released its post-preliminary analysis, and Petitioner and CPZ/SKF submitted post-preliminary comments on December 14, 2012, and post-preliminary rebuttal comments on December 18, 2012.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs as well as the post-preliminary comments and rebuttal comments filed by parties in this review are addressed in the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished from the People's Republic of China,'' dated concurrently with this notice (''Issues and Decision Memorandum''), which is hereby adopted by this notice. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum follows as an appendix to this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in the public memorandum, which is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Services System (''IA ACCESS''). Access to IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and is available to all parties in the Central Records Unit room 7046 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Period of Review

The POR is June 1, 2010, through May 31, 2011.

Scope of the Order

Imports covered by the order are shipments of tapered roller bearings and parts thereof, finished and unfinished, from the PRC; flange, take up cartridge, and hanger units incorporating tapered roller bearings; and tapered roller housings (except pillow blocks) incorporating tapered rollers, with or without spindles, whether or not for automotive use. These products are currently classifiable under Harmonized Tariff Schedule of the United States (''HTSUS'') item numbers 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.99.80.15[4] and 8708.99.80.80.[5] Although the HTSUS item numbers are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

PRC-Wide Entity

The Department initiated a review of Haining Automann and Zhejiang Zhaofeng but neither company provided a separate rate application. Because these companies do not already have separate rates, they remain part of the PRC-wide entity in this review. Accordingly, the PRC-wide entity is under review for these final results.

In NME proceedings, 'rates' may consist of a single dumping margin

[1] *See Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, From the People's Republic of China: Preliminary Results of the 2010–2011 Antidumping Duty Administrative Review, Rescission In Part, and Intent To Rescind in Part,* 77 FR 40579 (July 10, 2012) (''*Preliminary Results*'').

[2] *See* Memorandum from Abdelali Elouaradia, Office Director, to Paul Piquado, Assistant Secretary for Import Administration, ''Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished or Unfinished from the People's Republic of China: Post-Preliminary Targeted Dumping Analysis Memorandum,'' dated December 7, 2012.

[3] *See* Memorandum to the Record from Paul Piquado, AS for Import Administration, regarding ''Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Hurricane,'' dated October 31, 2012.

[4] Effective January 1, 2007, the HTSUS subheading 8708.99.8015 is renumbered as 8708.99.8115. *See* United States International Trade Commission (''USITC'') publication entitled, ''Modifications to the Harmonized Tariff Schedule of the United States Under Section 1206 of the Omnibus Trade and Competitiveness Act of 1988,'' USITC Publication 3898 (December 2006) found at *http://www.usitc.gov.*

[5] Effective January 1, 2007, the HTSUS subheading 8708.99.8080 is renumbered as 8708.99.8180; *see id.*

applicable to all exporters and producers.'' [6] Therefore, we assigned the PRC-wide entity a rate of 92.84 percent, the rate most recently assigned to the PRC-wide entity in this proceeding.[7] We have received no information since issuance of the *Preliminary Results* that provides a basis for reconsidering this determination, and will, therefore, continue to apply the rate of 92.84 percent to the PRC-wide entity, including Haining Automann and Zhejiang Zhaofeng.

Furthermore, in the *Preliminary Results,* we stated that, because all review requests for Tianshui Hailin were timely withdrawn, we intended to rescind this review with respect to Tianshui Hailin in the final results if the PRC-wide entity is not reviewed because Tianshui Hailin did not have a separate rate prior to the review. However, because Haining Automann and Zhejiang Zhaofeng remain part of the PRC-wide entity, the PRC-wide entity is under review. Therefore, we have not rescinded the review with respect to Tianshui Hailin, and it will remain under review as part of the PRC-wide entity.

Changes Since the Preliminary Results

Based on an analysis of the comments received, the Department has made certain changes to the margin calculation for CPZ/SKF. For the final results, the Department has made the following changes:

- We valued factory overhead, selling, general, and administrative expenses, and profit using the financial statements of NSK Bearing Manufacturing (Thailand) Co., Ltd. and JTEKT (Thailand) Co., Ltd.
- We valued CPZ/SKF's roller steel using Harmonized Tariff Schedule (''HTS'') category 7228.50.10 (''Other bars and rods, not further worked than cold-forming or cold-finished: of circular cross-section''), rather than HTS category 7227.90 (''Bars and rods of alloy steel (other than stainless), hot-rolled, in irregularly wound coils, NESOI'').
- We corrected the margin calculation to apply the weight-averaged percentages for CPZ/SKF's market economy and non-market economy purchases of steel bar to the cost of transporting the steel bar.
- The PRC-wide entity is under review.
- We are not rescinding this review, in part, for Tianshui Hailin.

Separate Rates

In the *Preliminary Results,* we found that ZXY, a separate-rate respondent, demonstrated its eligibility for a separate rate.[8] For the final results, we continue to find that the evidence placed on the record of this review by ZXY demonstrates an absence of both *de jure* and *de facto* government control with respect to its exports of the merchandise under review, and, thus continue to find that it is eligible for a separate rate.[9] As stated in the *Preliminary Results,* CPZ/SKF reported that it is wholly foreign-owned, and, therefore, consistent with the Department's practice, a further separate rate analysis was not necessary to determine whether CPZ/SKF's export activities were independent from government control, and we preliminarily granted a separate rate to CPZ/SKF.[10] For the final results, we continue to find that CPZ/SKF is eligible for a separate rate.

Margin for the Separate-Rate Companies

As discussed above, the Department continues to find that ZXY has demonstrated its eligibility for a separate rate. For the exporters subject to a review that are determined to be eligible for a separate rate, but are not selected as individually examined respondents, the Department generally weight-averages the rates calculated for the individually examined respondents, excluding any rates that are zero, *de minimis,* or based entirely on facts available.[11] Consistent with the Department's practice, as the separate rate, we have established a weighted-average dumping margin for ZXY based on the rate calculated for the individually examined respondent, CPZ/SKF.

Final Results of Review

We determine that the following weighted-average dumping margins exist for the period June 1, 2010, through May 31, 2011:

TRBs From the PRC

Exporter	Weighted-average dumping margin (percent)
Changshan Peer Bearing Co., Ltd.	15.28
Xiang Yang Automobile Bearing Co., Ltd.	15.28
PRC-wide entity*	92.84

*The PRC-wide entity includes Haining Automann, Zhejiang Zhaofeng, and Tianshui Hailin.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For any individually examined respondents whose weighted-average dumping margin is above *de minimis,* we calculated importer-specific assessment rates for merchandise subject to this review.[12] For Changshan Peer Bearing Co., Ltd., we calculated an *ad valorem* rate for each importer by dividing the total amount of dumping calculated for the importer's examined sales by the total entered values associated with those sales. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting *ad valorem* rate against the entered customs values for the subject merchandise. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review where an importer-specific assessment rate is above *de minimis* (*i.e.,* 0.50 percent). Where either the respondent's weighted-average dumping margin is zero or *de minimis,*[13] or an

[6] *See* 19 CFR 351.107(d).

[7] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 3987, 3988 (January 22, 2009). We note that this determination is currently in litigation at the Court of International Trade; however, a final decision from the court has not been issued.

[8] *See Preliminary Results,* 77 FR at 40581–82.

[9] *See id.*

[10] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Creatine Monohydrate from the People's Republic of China,* 64 FR 71104, 71104–05 (December 20, 1999) (where the respondent was wholly foreign-owned and, thus, qualified for a separate rate).

[11] *See, e.g., Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Results of New Shipper Review and Partial Rescission of Administrative Review,* 73 FR 8273, 8279 (February 13, 2008) (unchanged in *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review,* 73 FR 49162 (August 20, 2008)).

[12] In these final results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (''*Final Modification for Reviews*'').

[13] *See Final Modification for Reviews.*

importer-specific assessment rate is zero or *de minimis,*[14] we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

We will instruct CBP to liquidate entries of subject merchandise exported by the PRC-wide entity at the *ad valorem* rate of 92.84 percent of entered value.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For CPZ/SKF and ZXY, the cash deposit rate will be their respective rates established in the final results of this review, except if the rate is zero or *de minimis,* then no cash deposit will be required; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the PRC-wide entity of 92.84 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

We are issuing and publishing the final results and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 8, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

Comment 1: Targeted Dumping
Comment 2: Financial Ratios
Comment 3: Surrogate Value for Labor
Comment 4: Surrogate Value and Labor Hours for Roller Steel
Comment 5: Valuation of Steel for CPZ/PBCD-Produced Merchandise
Comment 6: Steel Bar Transportation

[FR Doc. 2013–00835 Filed 1–15–13; 8:45 am]

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[14] *See* 19 CFR 351.106(c)(2).

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the schedule and agenda for an open meeting of the United States Travel and Tourism Advisory Board (Board). The Board will meet to present updates on the work of its subcommittees and hear briefings from representatives of the U.S. government on the implementation of the National Travel and Tourism Strategy and the progress on implementing the President's Executive Order 13597 on travel and tourism. The agenda may change to accommodate Board business. The final agenda will be posted on the Department of Commerce Web site for the Board at *http://tinet.ita.doc.gov/TTAB/TTAB_Home.html,* at least one week in advance of the meeting.

DATES: February 4, 2013 1:30 p.m.–3:30 p.m. Eastern Standard Time (EST)

ADDRESSES: Biltmore Miami Hotels-Resort 1200 Anastasia Avenue, Miami, Florida 33134.

FOR FURTHER INFORMATION CONTACT: Jennifer Pilat, the United States Travel and Tourism Advisory Board, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: 202–482–4501, email: *jennifer.pilat@trade.gov.*

SUPPLEMENTARY INFORMATION:

Agenda: At the meeting, the Board will hear updates from its four subcommittees on travel facilitation, business climate, infrastructure and sustainability, and advocacy.

Background: The Board will advise the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be physically accessible to people with disabilities. All guests are requested to register in advance. Seating is limited and will be on a first come, first served basis. Requests for sign language interpretation, other auxiliary aids, or pre-registration, should be submitted no later than 5 p.m. EST on January 22, 2013 to Jennifer Pilat, the U.S. Travel and Tourism Advisory Board, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, telephone 202–482–4501, *OACIE@trade.gov.* Last minute requests will be accepted, but may be impossible to fill.

No time will be available for oral comments from members of the public attending the meeting. Any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Pilat at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EST on January 22, 2013, to ensure transmission to the Board prior to the meeting.

Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of Board meeting minutes will be available within 90 days of the meeting.

Dated: January 11, 2013.

Jennifer Pilat,

Executive Secretary, United States Travel and Tourism Advisory Board.

[FR Doc. 2013–00842 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC440

International Pacific Halibut Commission Appointments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of new call for nominations.

SUMMARY: In Spring 2012, NOAA Fisheries publicly solicited nominations for two presidential appointments to serve as U.S. Commissioners to the International Pacific Halibut Commission (IPHC). While the nomination list included many strong candidates, the combination of a number of factors resulted in the decision to re-initiate this public nomination process. These factors include heightened interest by diverse user groups, the lapse of time since original nominees expressed interest in an appointment, and considerations of balanced representation on the Commission. In their official IPHC duties, Commissioners represent the interests of the United States and all of its stakeholders in the Pacific halibut fishery, while working to develop the Pacific halibut stocks to levels that will permit the optimum yield from the Pacific halibut fishery. Thus, NOAA is again soliciting nominations for two individuals to serve as U.S. Commissioners to the IPHC.

DATES: Nominations must be received by February 15, 2013. A list of nominees will be published on the NMFS Alaska Regional Office Web site (*http://www.alaskafisheries.noaa.gov/*) on February 19, 2013. Public comments relating to this list of nominees will be accepted until March 18, 2013.

ADDRESSES: Nominations for U.S. Commissioners to the IPHC may be made in writing to Mr. Patrick E. Moran, Office of International Affairs, National Marine Fisheries Service, at 1315 East-West Highway, Silver Spring, MD 20910. Nominations may also be sent via fax (301–713–2313) or email (*IPHC2013nominations@noaa.gov*). Please send all public comments via email to *IPHC2013comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Patrick E. Moran, (301) 427–8370.

SUPPLEMENTARY INFORMATION:

Background

The IPHC is a bilateral regional fishery management organization established pursuant to the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention). The Convention was signed at Ottawa, Ontario, on March 2, 1953, and was amended by a Protocol Amending the Convention signed at Washington, DC, on March 29, 1979. The Convention's central objective is to develop the stocks of Pacific halibut in waters off the west coasts of Canada and the United States to levels that will permit the optimum yield from the Pacific halibut fishery and to maintain the stocks at those levels. The IPHC fulfills this objective in part by recommending Pacific halibut fishery conservation and management measures for approval by the United States and Canada. Pursuant to the Northern Pacific Halibut Act of 1982, the Secretary of State, with the concurrence of the Secretary of Commerce, may accept or reject, on behalf of the United States, conservation and management measures recommended by the IPHC. 16 U.S.C. 773b. Measures accepted by the Secretary of State are adopted as binding regulations governing fishing for Pacific halibut in Convention waters of the United States. 16 U.S.C. 773c(b)(1). More information on the IPHC can be found at *http://www.iphc.int.*

Section 773a of the Northern Pacific Halibut Act of 1982 (16 U.S.C. 773a) requires that the United States be represented on the IPHC by three U.S. Commissioners. U.S. Commissioners are appointed for a term not to exceed 2 years, but are eligible for reappointment. Of the Commissioners:

(1) One must be an official of the National Oceanic and Atmospheric Administration; and

(2) Two must be knowledgeable or experienced concerning the Northern Pacific halibut fishery; of these, one must be a resident of Alaska and the other shall be a nonresident of Alaska. Of the three commissioners described in paragraphs (1) and (2), one must also be a voting member of the North Pacific Fishery Management Council.

(3) Commissioners who are not Federal employees are not considered to be Federal employees except for the purposes of injury compensation or tort claims liability as provided in section 8101 *et seq.* of title 5 and section 2671 *et seq.* of title 28.

In their official IPHC duties, Commissioners represent the interests of the United States and all of its stakeholders in the Pacific halibut fishery. These duties require a modest amount of travel (typically two or three trips per year lasting less than a week), and travel expenses are paid by the U.S. Department of State. Commissioners receive no compensation for their services.

Nomination Process

NOAA Fisheries is currently accepting nominations for two U.S. Commissioners for the IPHC who are not officials of NOAA. Successful nominees will be considered for appointment by the President and (pending Presidential action) interim designation by the Department of State.

Nomination packages should provide details of an individual's knowledge and experience in the Pacific halibut fishery. Examples of such knowledge and/or experience could include (but are not limited to) such activities as: Participation in commercial, tribal, Community Development Quota (CDQ) and/or sport and charterboat halibut fishing operations; participation in halibut processing operations; and participation in Pacific halibut management activities

Nomination packages should document an individual's qualifications and state of residence. Self-nominations are acceptable, and current and former IPHC Commissioners are eligible for reappointment. Résumés, curriculum vitae, and/or letters of recommendation are useful but not required. Nomination packages will be evaluated on a case-by-case basis by officials in NOAA and the Department of Commerce who are familiar with the duties and responsibilities of IPHC Commissioners; evaluations will consider the aggregate of an individual's prior experience and knowledge of the Pacific halibut fishery, residency requirements, and any letters of recommendation provided. Nominees will be notified of their status (including rejection or approval) and any need for further information once the nomination process is complete.

Dated: January 10, 2013.

Jean-Pierre Plé,

Acting Director, Office of International Affairs, National Marine Fisheries Service.

[FR Doc. 2013–00756 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC062

Draft 2012 Marine Mammal Stock Assessment Reports

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of availability; reopening of public comment period.

SUMMARY: NMFS reviewed the Alaska, Atlantic, and Pacific regional marine mammal stock assessment reports (SARs) in accordance with the Marine Mammal Protection Act, and solicited public comment on draft 2012 SARs. Subsequently, SARs for ten stocks of marine mammals in the Atlantic region have been updated with revised abundance estimates and some corrections to bycatch estimates. NMFS solicits public comments on revised draft 2012 SARs for these ten stocks.

DATES: Comments must be received by April 16, 2013.

ADDRESSES: The ten revised 2012 draft SARs and supporting documentation are available in electronic form via the Internet at *http://www.nmfs.noaa.gov/pr/sars/draft.htm.* Copies of the ten revised draft Atlantic SARs may be requested from Gordon Waring, Northeast Fisheries Science Center, 166 Water St., Woods Hole, MA 02543.

You may submit comments, identified by NOAA–NMFS–2012–0119, by any of the following methods:

Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal. *http://www.regulations.gov.* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2012-0119,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

Mail: Send comments or requests for copies of reports to: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226, Attn: Stock Assessments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Shannon Bettridge, Office of Protected Resources, 301–427–8402, *Shannon.Bettridge@noaa.gov;* or Gordon Waring, 508–495–2311, *Gordon.Waring@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 117 of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*) requires NMFS and the U.S. Fish and Wildlife Service (FWS) to prepare stock assessments for each stock of marine mammals occurring in waters under the jurisdiction of the United States. These reports must contain information regarding the distribution and abundance of the stock, population growth rates and trends, estimates of annual human-caused mortality and serious injury from all sources, descriptions of the fisheries with which the stock interacts, and the status of the stock. Initial reports were completed in 1995.

The MMPA requires NMFS and FWS to review the SARs at least annually for strategic stocks and stocks for which significant new information is available, and at least once every three years for non-strategic stocks. The term strategic stock means a marine mammal stock: (A) For which the level of direct human-caused mortality exceeds the potential biological removal level; (B) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the Endangered Species Act. NMFS and the FWS are required to revise a SAR if the status of the stock has changed or can be more accurately determined. NMFS, in conjunction with the Alaska, Atlantic, and Pacific independent Scientific Review Groups (SRGs), reviewed the status of marine mammal stocks as required and revised reports in the Alaska, Atlantic, and Pacific regions to incorporate new information. NMFS solicited public comments on the draft 2012 SARs on August 7, 2012 (77 FR 47043); the 90-day public comment period closed on November 5, 2012.

Subsequent to soliciting public comment on the draft 2012 SARs, NMFS revised the 2011 abundance estimates and the 2010 northeast sink gillnet serious injury and mortality estimates for several Atlantic marine mammal stocks after discovering errors based upon further review of the abundance estimation methods and upon receiving updated bycatch data. This new information prompted the agency to correct and revise the SARs for the following marine mammal stocks affected by these updates: fin whale, western North Atlantic stock; sei whale, Nova Scotia stock; minke whale Canadian east coast stock; sperm whale, North Atlantic stock; Cuvier's beaked whale, western North Atlantic stock; Gervais' beaked whale, western North Atlantic stock; Sowerby's beaked whale, western North Atlantic stock; Risso's dolphin, western North Atlantic stock; Atlantic white-sided dolphin, western North Atlantic stock; and harbor porpoise, Gulf of Maine/Bay of Fundy stock. NMFS solicits public comment on the revised draft 2012 SARs for these ten stocks.

Summary of Revisions to Atlantic Reports

The following summarizes the revisions made to the original draft 2012 SARs. The 2011 abundance estimate for fin whale, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 3,628 (CV = 0.24) to 1,595 (CV = 0.33). This change does not affect the minimum population estimate (Nmin) or the potential biological removal level (PBR) calculation, as the 2007 estimate is still considered the best abundance estimate and is used to calculate Nmin and PBR.

The abundance estimate for sei whale, Nova Scotia stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 467 (CV = 0.67) to 357 (CV = 0.52); Nmin changed from 279 to 236; and PBR changed from 0.6 to 0.5.

The 2011 abundance estimate for minke whale, Canadian east coast stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 7,817 (CV = 0.29) to 2,591 (CV = 0.81). This change does not affect Nmin or the PBR calculation, as the 2007 estimate is still considered the best abundance estimate and is used to calculate Nmin and PBR.

The abundance estimate for sperm whale, North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 1,584 (CV = 0.40) to 1,593 (CV = 0.36); Nmin changed from 1,142 to 1,187; and PBR changed from 2.3 to 2.4.

The abundance estimate for Cuvier's beaked whale, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 5,611 (CV = 0.42) to 4,962 (CV = 0.37); Nmin changed from 3,992 to 3,670; and PBR declined from 40 to 37.

The abundance estimate for Gervais' beaked whale, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 1,945 (CV = 1.0) to 1,847 (CV =

0.96); Nmin changed from 966 to 935; and PBR changed from 9.7 to 9.4.

The abundance estimate for Sowerby's beaked whale, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 3,748 (CV = 0.86) to 3,653 (CV = 0.69); Nmin increased from 2,008 to 2,160; and PBR increased from 20 to 22.

The abundance estimate for Risso's dolphin, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 17,734 (CV = 0.42) to 15,197 (CV = 0.55); Nmin decreased from 12,630 to 9,857; and PBR changed from 121 to 95.

The abundance estimate for Atlantic white-sided dolphin, western North Atlantic stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 45,592 (CV = 0.54) to 48,819 (CV = 0.61); Nmin increased from 29,806 to 30,403; and PBR increased from 298 to 304. Total annual estimated average fishery-related mortality or serious injury to this stock during 2006–2010 changed from 213 to 212. Average annual estimated fishery-related mortality attributed to the Northeast sink gillnet fishery during 2006–2010 decreased from 39 to 38 white-sided dolphins per year.

The abundance estimate for harbor porpoise, Gulf of Maine/Bay of Fundy stock, in the draft 2012 SAR (77 FR 47043, August 7, 2012) has changed from 61,959 (CV = 0.32) to 79,833 (CV = 0.32); Nmin increased from 47,635 to 61,415; and PBR changed from 548 to 706. The total annual estimated average human-caused mortality changed from 840 to 835 harbor porpoises per year; 791 attributed to U.S. fisheries (changed from 796). The average annual harbor porpoise mortality and serious injury attributed to the Northeast sink gillnet fishery from 2006 to 2010 changed from 515 to 511 (CV = 0.17).

The average annual harbor porpoise mortality and serious injury attributed to the mid-Atlantic gillnet fishery listed in the draft 2012 SAR (77 FR 47043, August 7, 2012) from 2006 to 2010 has changed from 276 to 275 (CV = 0.35).

Dated: January 10, 2013.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–00705 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC434

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Scoping Process; Mid-Atlantic Fishery Management Council; Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council (Mid-Atlantic Council) announces its intention to prepare, in cooperation with NMFS, an EIS in accordance with the National Environmental Policy Act to assess potential effects on the human environment of alternative measures to protect deep-sea corals in the Mid-Atlantic region.

This notice announces a public process for determining the scope of issues to be addressed, and for identifying the significant issues related to deep-sea coral protections in the Mid-Atlantic. This notice is to alert the interested public of the scoping process, the development of the Draft EIS, and to provide for public participation in that process. If, during development of the Draft EIS, it can be determined that the alternatives are not expected to have significant impacts on the human environment, an Environmental Assessment (EA) may be prepared in place of an EIS. This determination will depend on the scope of issues raised and the alternatives developed. Information obtained during the scoping process will be used to develop either an EIS or an EA as appropriate. This action is necessary to provide analytical support for an amendment (Amendment 16) to the Fishery Management Plan (FMP) for Atlantic Mackerel, Squid, and Butterfish (MSB), which addresses protections of deep-sea corals from the impacts of fishing gear.

DATES: Written comments must be received on or before 11:59 p.m., EST, on February 15, 2013. Two public scoping meetings will be held during this comment period. See **SUPPLEMENTARY INFORMATION** for dates, times, and locations.

ADDRESSES: Written comments may be sent by any of the following methods:

- Email to the following address: *nmfs.ner.msbam16@noaa.gov;*
- Mail or hand deliver to Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. Mark the outside of the envelope ''Deep Sea Corals Amendment Scoping Comments''; or
- Fax to (302) 674–5399.

The scoping document may also be obtained from the Mid-Atlantic Council office at the previously provided address, or by request to the Mid-Atlantic Council by telephone (302) 674–2331, or via the Internet at *http://www.mafmc.org/fmp/msb.htm.*

Comments may also be provided verbally at either of the two public scoping meetings. See **SUPPLEMENTARY INFORMATION** for dates, times, and locations.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher M. Moore, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901, (telephone 302–674–2331).

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Council has initiated this amendment to minimize the impacts of fishing gear on deep-sea corals within the Council's jurisdiction. The Mid-Atlantic Council and the New England Fishery Management Council (New England Council) have developed a Memorandum of Understanding (MOU) identifying areas of consensus and common strategy related to conservation of corals and mitigation of the negative impacts of fishery/coral interactions. The terms of the MOU include defined areas of jurisdiction for deep-sea coral protection measures, aligning with the Mid-Atlantic and New England Council region boundaries as defined in 50 CFR 600.105.

The New England Council began developing alternatives for deep-sea coral protections as part of their Essential Fish Habitat (EFH) Omnibus Amendment 2, and at their September 2012 meeting, voted to split the range of alternatives pertaining to deep sea corals into a separate omnibus amendment. The Mid-Atlantic Council will develop alternatives applicable to areas south of the inter-council boundary with the New England Council, with the understanding that the New England Council will implement coral-related measures north of this boundary.

At this time, the Mid-Atlantic Council is expected to consider several types of management measures, including, but not limited to:

- No action; no additional measures would be adopted.
- Designation of deep-sea coral protection zones, under the

discretionary authority described in section 303(b)(2)(B) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA), where fishing may be restricted in order to protect deep-sea corals from physical damage caused by fishing gear. Such zones would be located within the geographical range of the MSB fishery, as described in the FMP. However, management measures may apply to any MSA-regulated fishing activity within this range. Therefore, any measures pursued under this authority would likely apply to all federally managed fisheries within the geographic range of the MSB fisheries. The geographical range of this fishery includes the coastal and EEZ waters of the U.S. East Coast, with a core fishery management area from North Carolina to Maine.

- Designation of deep-sea corals as a component of EFH or as Habitat Areas of Particular Concern (HAPCs).
- Measures to minimize bycatch of deep-sea coral species.
- Special access programs to provide for continued fishing in or near deep-sea coral areas for specific fisheries or gear types.
- Exploratory fishing programs to allow for future development of new fisheries in a way that protects deep-sea corals.

The Mid-Atlantic Council is seeking comments on the scope of alternatives to be considered in this amendment, as well as general comments or concerns relating to deep-sea coral protections in the mid-Atlantic.

Scoping Meetings

Two scoping meetings to facilitate public comment will be held on the following dates and locations:

1. February 5, 2013, 7–9 p.m., via webinar; connection information to be available at *http://www.mafmc.org/meetings/meetings.htm* or by contacting the Mid-Atlantic Council (see **ADDRESSES**);

2. February 13, 2013, 4 p.m., Embassy Suites Hampton Roads, 1700 Coliseum Drive, Hampton, VA 23666.

Special Accommodations

The scoping meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders (302–674–2331 ext. 18) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 9, 2013.

Emily H. Menashes,

Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–00808 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC443

Marine Fisheries Advisory Committee

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of open public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee (MAFAC). The members will discuss and provide advice on issues outlined in the agenda below.

DATES: The meeting is scheduled for January 30, 2013, 3–4 p.m., Eastern Daylight Time.

ADDRESSES: Conference call. Public access is available at 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Mark Holliday, (301) 427–8004; email: *Mark.Holliday@noaa.gov*.

SUPPLEMENTARY INFORMATION: The MAFAC was established by the Secretary of Commerce (Secretary), and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The complete charter and other information are located online at *http://www.nmfs.noaa.gov/ocs/mafac/*.

Matters To Be Considered

The Committee is convening to recommend a list of new members to participate on the Recreational Fisheries Working Group for submission to the NOAA Fisheries Assistant Administrator. This agenda is subject to change.

Dated: January 10, 2013.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, performing the functions and duties of the Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–00757 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XB173

Marine Mammals; File No. 16919

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to Eye of the Whale (Olga von Ziegesar, Responsible Party and Principal Investigator), P.O. Box 15191, Fitz Creek, AK 99603 to conduct research on humpback whales (*Megaptera novaeangliae*).

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)427–8401; fax (301)713–0376; and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907)586–7221; fax (907)586–7249.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Carrie Hubard, (301)427–8401.

SUPPLEMENTARY INFORMATION: On May 11, 2012, notice was published in the **Federal Register** (77 FR 27717) that a request for a permit to conduct research on humpback whales had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The Permit Holder has been issued a five-year scientific research permit to continue a long-term census of humpback whales in Prince William Sound and adjacent waters of Alaska. Researchers are authorized 200 takes annually to closely approach whales by vessel for counts, photo-identification and behavioral observation. The purpose of the work is to better define whale abundance, distribution, reoccurrence of old individuals vs. new individuals, feeding habits, vital rates, associations between animals, and sex of individual whales.

An environmental assessment (EA) was prepared analyzing the effects of the permitted activities on the human environment in compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Based on the analyses in the EA, NMFS determined that issuance of the permit would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact (FONSI), signed on October 9, 2012.

As required by the ESA, issuance of this permit was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: January 10, 2013.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–00830 Filed 1–15–13; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Financial Education Content Needs Survey

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before February 15, 2013.

ADDRESSES: Send comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, to the addresses below. Please refer to this **Federal Register** notice in any correspondence.

Comments may be submitted to: Nisha Smalls, Office of Consumer Outreach, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581;

Comments may also be submitted by any of the following methods:

The agency's Web site at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Mail: Natise Stowe, Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

Hand Delivery/Courier: Same as mail above.

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Please submit your comments using only one method and identity that it is for the renewal of this **Federal Register** notice.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

FOR FURTHER INFORMATION OR A COPY CONTACT: Nisha Smalls, Office of Consumer Outreach, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581, (202) 418–5895; FAX: (202) 418–5541; email: *nsmalls@cftc.gov* and refer to this **Federal Register** notice.

SUPPLEMENTARY INFORMATION:

Abstract: In accordance with 7 U.S.C. 26, the CFTC is posing survey questions to the public. Questions included in the survey will inquire as to how often the respondents would like to receive content from CFTC, the format in which the respondents would like to receive information, and the topics the information should cover.

The Office of Consumer Outreach develops campaigns to change consumer behaviors, so that consumers can better avoid fraud as defined under the Commodities Exchange Act. The first campaign from the Office of Consumer Outreach involves utilizing government and non-profit agency distribution methods to provide anti-fraud information to consumers. This survey will assist the Office of Consumer Outreach in determining how the government and non-profit agencies would like to receive the anti-fraud information from the CFTC.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on October 30, 2012.

Burden statement: The Commission estimates the burden of this collection of information as follows:

Regulations (17 CFR)	Estimated number of respondents	Total annual responses	Estimated number of hours per response	Annual burden
Survey	500	500	.25	125

There are no capital costs or operating and maintenance costs associated with this collection. The proposed survey will consist of the following questions:

BILLING CODE 6531–01–P

[1] *See* 17 CFR 145.9.

Financial Education Content Needs Survey

1. Do you need financial education content to provide to your constituents?

- ☐ Yes
- ☐ No

*

2. Are you interested in receiving financial education content from the U.S. Commodity Futures Trading Commission (CFTC)?

- ☐ Yes
- ☐ No

3. Are you interested in receiving financial education content developed specifically for any of the audiences below? Please select all that apply.

- ☐ Seniors
- ☐ Youth
- ☐ Military Service Members

Other (please specify)

4. How would you like the CFTC to provide financial education content to you?

- ☐ Email with PDF attachment(s)
- ☐ Email with Microsoft Word attachment(s)
- ☐ Content included within the body of an email
- ☐ Links to the content on CFTC's website

Other (please specify)

5. In what format would you like the CFTC to provide financial education content to you?

- ☐ Long form document/copy from which you can pull the information you require
- ☐ Copy that is formatted for specific uses such as articles, email, social media, etc.
- ☐ Long form document/copy AND formatted copy for specific uses such as articles, email, social media, etc.

Other (please specify)

6. How often would you like the CFTC to send you financial education content?

- ☐ Weekly
- ☐ Biweekly
- ☐ Monthly
- ☐ Bimonthly

Other (please specify)

7. Please rate your constituent's interest in the following commodity futures trading topics:

	Very High	High	Neutral	Low	Very Low	N/A
News about the CFTC	☐ Very High	☐ High	☐ Neutral	☐ Low	☐ Very Low	☐ N/A
Trading information (futures, foreign currency exchange, precious metals, etc.)	☐ Very High	☐ High	☐ Neutral	☐ Low	☐ Very Low	☐ N/A
Fraud Avoidance	☐ Very High	☐ High	☐ Neutral	☐ Low	☐ Very Low	☐ N/A
Futures trading restitution options	☐ Very High	☐ High	☐ Neutral	☐ Low	☐ Very Low	☐ N/A

Other (please specify)

*

8. What channel(s) do you use to communicate with your constituents? Please select all that apply.

- ☐ Website
- ☐ Email/eNewsletter
- ☐ Printed newsletter
- ☐ Printed materials (brochures, booklets, flyers, etc.)

- ☐ Online paid media (banner ads, text links, etc.)
- ☐ Print paid media (magazine ads, newspaper ads, etc.)
- ☐ Earned media (press releases, omnipolls, etc.)
- ☐ Social media
- ☐ Webinars
- ☐ Events
- ☐ None of the above

Other (please specify)

*

9. How often do you use the channels below to communicate with your constituents?

	Weekly	Monthly	Quarterly	N/A
Website	☐	☐	☐	☐
Email/eNewsletter	☐	☐	☐	☐
Printed newsletter	☐	☐	☐	☐
Printed materials	☐	☐	☐	☐
Online paid media	☐	☐	☐	☐
Print paid media	☐	☐	☐	☐
Earned media	☐	☐	☐	☐
Social media	☐	☐	☐	☐
Webinars	☐	☐	☐	☐
Events	☐	☐	☐	☐

Other (please specify)

10. Should anyone else within your organization receive financial education content from the CFTC? If yes, please provide their names and email addresses.

Yes

No

Done

Dated: January 10, 2013.

Stacy D. Yochum,

Counsel to the Executive Director.

[FR Doc. 2013–00802 Filed 1–15–13; 8:45 am]

BILLING CODE 6531–01–C

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

CNCS is soliciting comments concerning its proposed assessment of Training and Technical Assistance (TTA) investments. At present, assessment of TTA consists of analysis of client satisfaction feedback with aggregations of post training-participant evaluations collected thru TTA Providers funded under cooperative agreements. TTA Providers are required to report post-training outputs and customer satisfaction data covered under OMB Control #3045–0105. Additional pre- and post-knowledge gain assessments instruments are proposed to collect evidence of any learning that actually occurred as a result of the training or return on investment for the training cost.

Copies of the information collection request can be obtained by contacting the office listed in the addresses section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by March 18, 2013.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service; Attention: Ralph Morales, Associate Director for Administration and Budget, Room 9703; 1201 New York Avenue NW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) *By fax to:* (202) 606–3477, Attention: Ralph Morales, Associate Director for Budget and Administration.

(4) Electronically through *http://www.regulations.gov* or *rmorales@cns.gov*. Individuals who use a telecommunications device for the deaf (TTY–TTD) may call 1–800–833–3722 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ralph Morales, (202) 606–6829, or by email at *rmorales@cns.gov*.

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses).

Background

CNCS provides TTA to its grantees in topic areas related to program quality, compliance, and performance measurement through an online learning site as well as through face-to-face sessions conducted by consultants procured through contractors or cooperative agreements as well as CNCS staff. The effectiveness of this training and technical assistance is currently evaluated through analysis of client satisfaction feedback in aggregate form (see OMB Control #3045–0105).

Current Action

In addition to the data currently being collected, CNCS wishes to evaluate the knowledge gains of participants who partake in the training and technical assistance programs by administering pre- and post-test instruments to participants. CNCS will collect this information through specific online courses or face-to-face training designated as a part of the CNCS core curriculum. If the training is conducted through a grantee or contractor the contractor will collect on CNCS' behalf. However CNCS will aggregate data across TTA activities for internal analysis. If the CNCS should itself conduct training and/or technical assistance, the same pre- and post-test instruments would be used to gather knowledge gain data. The information collection will be used to further evaluate the effectiveness of the Corporation's training and technical assistance offerings to participants.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: Assessing the Impact of Training and Technical Assistance.

OMB Number: New.

Agency Number: None.

Affected Public: Current/prospective training and technical assistance providers.

Total Respondents: 10,000.

Frequency: Annually.

Average Time Per Response: Five minutes for the pre-test and 5 minutes for the post-test for a total of 10 minutes.

Estimated Total Burden Hours: 1666.67 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 4, 2013.

Gretchen Van der Veer,

Director, Leadership Development and Training.

[FR Doc. 2013–00843 Filed 1–15–13; 8:45 am]

BILLING CODE 6050–$$–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) titled ''National Service Criminal History Check Recordkeeping Requirement'' for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling CNCS, Aaron Olszewski, at (202) 606–6709 or email to *aolszewski@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods by February 15, 2013:

(1) *By fax to:* (202) 395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; and

(2) *Electronically by email to: smar@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Comments

A 60-day public comment Notice was published in the **Federal Register** on November 9, 2012. This comment period ended January 8, 2013. No public comments were received from this Notice.

Description: CNCS requests renewal of the recordkeeping requirement previously approved under an emergency clearance.

The requirements will be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on March 31, 2013.

Type of Review: Renewal of Approved Recordkeeping Requirement.

Agency: Corporation for National and Community Service.

Title: National Service Criminal History Check Recordkeeping Requirement.

OMB Number: 3045–0145.

Agency Number: None.

Affected Public: CNCS Grantees and Subgrantees.

Total Respondents: 112,357.

Frequency: Three times per covered position.

Average Time Per Response: Five minutes.

Estimated Total Burden Hours: 28,089 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: January 10, 2013.

Valerie Green,

General Counsel.

[FR Doc. 2013–00775 Filed 1–15–13; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Office of the Secretary

U.S. Court of Appeals for the Armed Forces Code Committee Meeting

ACTION: Notice of public meeting.

SUMMARY: This notice announces the forthcoming public meeting of the Code Committee established by Article 146(a), Uniform Code of Military Justice, 10 U.S.C. 946(a), to be held at the Courthouse of the United States Court of Appeals for the Armed Forces, 450 E Street NW., Washington, DC 20442–0001, at 10:00 a.m. on Tuesday, March 5, 2013. The agenda for this meeting will include consideration of proposed changes to the Uniform Code of Military Justice and the Manual for Courts-Martial, United States, and other matters relating to the operation of the Uniform Code of Military Justice throughout the Armed Forces.

FOR FURTHER INFORMATION CONTACT: William A. DeCicco, Clerk of Court, United States Court of Appeals for the Armed Forces, 450 E Street Northwest, Washington, DC 20442–000l, telephone (202) 761–1448.

Dated: January 11, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–00814 Filed 1–15–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent to Prepare a Supplement to the Gulf of Alaska Navy Training Activities Environmental Impact Statement/Overseas Environmental Impact Statement and to Announce Public Scoping

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations (40 Code of Federal Regulations (CFR) parts 1500–1508), and Executive Order 12114, the Department of the Navy (DoN) announces its intent to prepare a supplement to the 2011 Gulf of Alaska Navy Training Activities Environmental Impact Statement (EIS)/Overseas Environmental Impact Statement (OEIS). The SEIS/OEIS will support authorization of incidental takes of marine mammals under the Marine Mammal Protection Act and incidental takes of threatened and endangered marine species, under the Endangered Species Act. These federal regulatory permits and authorizations expire in May 2016. The DoN will evaluate new, relevant information and incorporate that information into revised analyses where appropriate. The SEIS/OEIS will also analyze data using an acoustic model not available for the 2011 EIS/OEIS, the Navy Acoustics Effects Model, to estimate potential marine species effects.

The DoN has requested the National Marine Fisheries Service be a cooperating agency in preparation of this SEIS/OEIS pursuant to 40 CFR § 1501.6.

Dates and Addresses: Given that the DoN's Proposed Action and alternatives have not changed, public scoping meetings will not be held, but public comments will be accepted during the scoping period from January 16, 2013 to March 18, 2013. The DoN will accept scoping comments through the Web site

and mail. Additional information concerning acceptance of scoping comments is available on the SEIS/OEIS web page located at: *http://www.GOAEIS.com.*

FOR FURTHER INFORMATION CONTACT: Mrs. Amy Burt, Naval Facilities Engineering Command, Northwest, 1101 Tautog Circle, Suite 203, Silverdale, Washington 98315–1101, Attn: GOA SEIS/OEIS Project Manager.

SUPPLEMENTARY INFORMATION: This SEIS/OEIS is a supplement to the 2011 Gulf of Alaska Navy Training Activities EIS/OEIS and Record of Decision. The SEIS/OEIS will be used to renew current regulatory permits and authorizations and to support U.S. Pacific Command, Northern Command, and Joint Task Force Commander training requirements to achieve and maintain Fleet readiness as required by Title 10 of the U.S. Code. The DoN's Proposed Action is to continue DoN training in the Gulf of Alaska as detailed under the Preferred Alternative in the 2011 EIS/OEIS, and implemented with the 2011 EIS/OEIS Record of Decision. The Proposed Action does not alter the DoN's original purpose and need or alternative analysis as discussed in the 2011 EIS/OEIS; therefore, the alternative analysis presented in the EIS/OEIS remains relevant and is not proposed to be reanalyzed in the SEIS/OEIS. The continued conduct of at-sea joint exercises in the Gulf of Alaska is needed to support the training of combat-capable naval forces. An SEIS/OEIS is considered to be the appropriate document as the DoN's Proposed Action may significantly impact or harm marine resources.

Resources that will be addressed due to the potential effects from the Proposed Action, new available scientific data, and modeling results will include, but are not limited to, marine mammals and threatened and endangered species.

The Gulf of Alaska (GOA) Navy Training Activities SEIS/OEIS Study Area consists of three components: (1) the GOA Temporary Maritime Activities Area, (2) U.S. Air Force over-land Special Use Airspace and air routes over the GOA and State of Alaska, and (3) U.S. Army training lands underlying Special Use Airspace. Collectively, for the purposes of the SEIS/OEIS, these areas are referred to as the Alaska Training Areas. The U.S. Air Force Special Use Airspace and U.S. Army training lands were previously analyzed for NEPA purposes under separate environmental documents and are not included in the analysis in this SEIS/OEIS but are included by reference.

The scoping process will be used to identify community concerns and local issues that will be addressed in the SEIS/OEIS. Federal agencies, Alaska Native Tribes, state agencies, local agencies, the public, and interested persons are encouraged to provide comments to the DoN to identify specific issues or topics of environmental concern. All comments, provided via the Web site or in writing via postal submission, will receive the same consideration during SEIS/OEIS preparation. Written comments must be postmarked, and Web site comments must be completed no later than March 18, 2013. Written comments should be mailed to: Mrs. Amy Burt, Naval Facilities Engineering Command, Northwest, 1101 Tautog Circle, Suite 203, Silverdale, Washington 98315–1101, Attn: GOA SEIS/OEIS Project Manager.

Dated: January 11, 2013.

C. K. Chiappetta,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2013–00847 Filed 1–15–13; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Board of Visitors of Marine Corps University

AGENCY: Department of the Navy, DoD.

ACTION: Notice of Open Meeting.

SUMMARY: The Board of Visitors of the Marine Corps University will meet to review, develop and provide recommendations on all aspects of the academic and administrative policies of the University; examine all aspects of professional military education operations; and provide such oversight and advice, as is necessary, to facilitate high educational standards and cost effective operations. The Board will be focusing primarily on the internal procedures of Marine Corps University. All sessions of the meeting will be open to the public.

DATES: The meeting will be held on Friday, February 22, 2013 from 9:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting will be held at the Crystal Gateway Marriott hotel in Crystal City, Virginia. The address is: 1700 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Joel Westa, Director of Academic Support, Marine Corps University Board of Visitors, 2076 South Street, Quantico, Virginia 22134, telephone number 703–784–4037.

Dated: January 9, 2013.

C.K. Chiappetta,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2013–00810 Filed 1–15–13; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2012–ICCD–0051]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for Client Assistance Program

AGENCY: Department of Education (ED), Office of Special Education and Rehabilitative Services (OSERS).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 15, 2013.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2012–ICCD–0051 or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E117, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: Electronically mail *ICDocketMgr@ed.gov.* Please do not send comments here.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize

the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Client Assistance Program.

OMB Control Number: 1820–0520.

Type of Review: Extension without change of an existing collection of information.

Respondents/Affected Public: State, Local or Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 9.

Abstract: This form is used by states to request funds to establish and carry out Client Assistance Programs (CAP). CAP is mandated by the Rehabilitation Act of 1973, as amended (Rehabilitation Act), to assist consumers and applicants in their relationships with projects, programs and services provided under the Rehabilitation Act including the Vocational Rehabilitation program.

Dated: January 9, 2013.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–00777 Filed 1–15–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2012–ICCD–0049]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Form for Maintenance of Effort Waiver Requests Under the Elementary and Secondary Education Act of 1965, as Amended

AGENCY: Department of Education (ED), Office of Elementary and Secondary Education (OESE).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 15, 2013.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2012–ICCD–0049 or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E117, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: Electronically mail *ICDocketMgr@ed.gov.* Please do not send comments here.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Form for Maintenance of Effort Waiver Requests under the Elementary and Secondary Education Act of 1965, as amended.

OMB Control Number: 1810–0693.

Type of Review: Revision of an existing collection of information.

Respondents/Affected Public: State, Local or Tribal Governments.

Total Estimated Number of Annual Responses: 202.

Total Estimated Number of Annual Burden Hours: 5,360.

Abstract: Section 9521(a) of the Elementary and Secondary Education Act of 1965, as amended (ESEA) provides that a local educational agency (LEA) may receive funds under Title I, Part A and other ESEA covered programs for any fiscal year only if the State educational agency (SEA) finds that either the combined fiscal effort per student or the aggregate expenditures of the LEA with respect to the provision of free public education by the LEA for the preceding fiscal year was not less than 90 percent of the combined fiscal effort or aggregate expenditures for the second preceding fiscal year. This provision is the maintenance of effort (MOE) requirement for LEAs under the ESEA.

If an LEA fails to meet the MOE requirement, under section 9521(b) of the ESEA, the SEA must reduce the amount of funds allocated under the programs covered by the MOE requirement in any fiscal year in the exact proportion by which the LEA fails to maintain effort by falling below 90 percent of either the combined fiscal effort per student or aggregate expenditures. In reducing an LEA's allocation because it failed to meet the MOE requirement, the SEA uses the measure most favorable to the LEA.

Section 9521(c) gives the U.S. Department of Education (ED) the authority to waive the ESEA's MOE requirement for an LEA if it would be equitable to grant the waiver due to an exceptional or uncontrollable circumstance such as a natural disaster or a precipitous decline in the LEA's

financial resources. Once an MOE waiver is granted, the reduction required by section 9521(b) does not occur for that year.

To review MOE waiver requests, ED relies primarily on expenditure, revenue, and other data relevant to an LEA's request provided by the SEA. To assist SEAs with submitting this information, ED developed an MOE waiver form as part of the 2009 Title I, Part A Waiver Guidance, which covered a range of waivers that ED invited at that time.

The purpose of this collection is to renew approval for the MOE waiver form. ED believes that the proposed form, which is slightly modified from the currently approved version, will enable an SEA to provide the information needed in an efficient manner.

Dated: January 9, 2013.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–00776 Filed 1–15–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2013–ICCD–0001]

Agency Information Collection Activities; Comment Request; Formula Grant for the Electronic Application System for Indian Education (EASIE)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 18, 2013.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0001 or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E117, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: Electronically mail *ICDocketMgr@ed.gov.* Please do not send comments here.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Formula Grant for the Electronic Application System for Indian Education (EASIE).

OMB Control Number: 1810–0021.

Type of Review: an extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 11,300.

Total Estimated Number of Annual Burden Hours: 9,590.

Abstract: The Office of Indian Education (OIE) of the Department of Education (ED) requests clearance for the Indian Education Formula Grant Application authorized under Title VII, Part A, Subpart 1 of the Elementary and Secondary Education Act, as amended (ESEA). The Indian Education Formula Grant (CFDA 84.060A), is not competitive or discretionary and requires the annual submission of the application from the Local Education Agency and or Tribe. The funds under this program assist applicants to provide Indian students with the opportunity to meet the same challenging state standards as all other students and meet the unique educational and culturally related academic needs of American Indian and Alaska Native students. The amount of the award for each applicant is determined by a formula based on the reported number of American Indian/Alaska Native students identified in the application, the state per pupil expenditure, and the total appropriation available. The information collection is also necessary to meet the Government Performance and Results Act (GPRA) requirements. The collection is authorized by section 7114(a) of the ESEA, 20 U.S.C .7424(a), and by section 4 of the Government Performance and Results Act of 1993 (GPRA).

Dated: January 10, 2013.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–00773 Filed 1–15–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology (PCAST): Correction

AGENCY: Department of Energy.

ACTION: Notice of Open Teleconference: Correction.

SUMMARY: On January 10, 2012, the Department of Energy (DOE) published a notice of open teleconference for the President's Council of Advisors on Science and Technology (PCAST) to be held on January 24, 2013. This document makes several corrections to that notice.

FOR FURTHER INFORMATION CONTACT: Dr. Amber Hartman Scholz, PCAST Acting Executive Director, by email at: *ascholz@ostp.eop.gov*, or by telephone: (202) 456–4444.

Corrections

In the **Federal Register** of January 10, 2013, in FR Doc. 2013–00329, on pages 2259–2260, please make the following corrections:

Under **DATES**, page 2259, second column, first paragraph, eighth line, the date has changed. The new date is Wednesday, January 23, 2013.

Under **SUPPLEMENTARY INFORMATION**, *Proposed Schedule and Agenda* heading, page 2259, third column, first paragraph, fifth line, please change date to January 24, 2013.

Under the *Public Comments* heading, third column, second paragraph, second line, please change date to January 24, 2013.

Under the *Oral Comments* heading, page 2259, third column, sixth line, please change date to January 23, 2013.

Under the *Written Comments* heading, page 2260, first column, first paragraph, fifth line, please change date to January 23, 2013.

Issued in Washington, DC on January 10, 2013.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2013–00811 Filed 1–15–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–60–000.
Applicants: ITC Midwest LLC.
Description: Application Pursuant to Section 203 of the Federal Power Act of ITC Midwest LLC for North Madrid Substation Relay Acquisition.
Filed Date: 1/9/13.
Accession Number: 20130109–5089.
Comments Due: 5 p.m. ET 1/30/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER09–1224–004.
Applicants: Energy Services, Inc., Entergy Operating Companies.
Description: Entergy Services, Inc. submits compliance filing on behalf of Entergy Operating Companies.
Filed Date: 7/6/12.
Accession Number: 20120706–5098.
Comments Due: 5 p.m. ET 1/23/13.

Docket Numbers: ER10–2794–010; ER10–2849–009; ER11–2028–010; ER12–1825–008.
Applicants: EDF Trading North America, LLC, EDF Industrial Power Services (NY), LLC, EDF Industrial Power Services (IL), LLC, EDF Industrial Power Services (CA), LLC.
Description: Updated Market Power Analysis for the Southwest Power Pool, Inc. Region of EDF Trading North America, LLC, et al.
Filed Date: 1/8/13.
Accession Number: 20130108–5162.
Comments Due: 5 p.m. ET 3/11/13.

Docket Numbers: ER13–17–001.
Applicants: Niagara Wind Power, LLC.
Description: Compliance Filing to be effective 3/11/2013.
Filed Date: 1/9/13.
Accession Number: 20130109–5008.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: ER13–733–000.
Applicants: Silver Bear Power, LLC.
Description: New filing 1 to be effective 3/1/2013.
Filed Date: 1/9/13.
Accession Number: 20130109–5011.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: ER13–734–000.
Applicants: Atlantic Coast Energy Corporation.
*Description:*Atlantic Coast Energy Corporation submits tariff filing per 35.12: Initial Application for MBR Authority to be effective 1/31/2013.
Filed Date: 1/9/13.
Accession Number: 20130109–5073.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: ER13–735–000.
Applicants: ISO New England Inc.
*Description:*ISO New England Inc. Resource Termination Filing—Concord.
Filed Date: 1/9/13.
Accession Number: 20130109–5082.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: ER13–736–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.
*Description:*Niagara Mohawk Power Corporation submits tariff filing per 35.13(a)(2)(iii: LGIA among NiMo, Alliance, AG Power, Seneca and Sterling Power to be effective 6/8/2012.
Filed Date: 1/9/13.
Accession Number: 20130109–5105.
Comments Due: 5 p.m. ET 1/30/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 9, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00759 Filed 1–15–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–740–000]

EnerPenn USA LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of EnerPenn USA LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is January 30, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email

FERCOnlineSupport@ferc.gov. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 10, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00758 Filed 1–15–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–739–000]

Texpo Power, LP; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Texpo Power, LP's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is January 30, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 10, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–00760 Filed 1–15–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Meeting, Notice of Vote, Explanation of Action Closing Meeting and List of Persons To Attend

The following notice of meeting is published pursuant to Section 3(a) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: January 17, 2013.

* **Note**—The Closed meeting will follow the Open meeting.

PLACE: Room 3M–2A&B, 888 First Street NE., Washington, DC 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Non-Public Investigations and Inquiries, Enforcement Related Matters.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

Chairman Wellinghoff and Commissioners Moeller, Norris, LaFleur, and Clark voted to hold a closed meeting on January 17, 2013. The certification of the General Counsel explaining the action closing the meeting is available for public inspection in the Commission's Public Reference Room at 888 First Street NE., Washington, DC 20426.

The Chairman and the Commissioners, their assistants, the Commission's Secretary, the General Counsel and members of his staff, and a stenographer are expected to attend the meeting. Other staff members from the Commission's program offices who will advise the Commissioners in the matters discussed will also be present.

Issued: January 10, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–00743 Filed 1–15–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0534; FRL–9526–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Surface Coating of Plastic Parts for Business Machines (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before February 15, 2013.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0534, to: (1) EPA online, using *www.regulations.gov* (our preferred method), or by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the

procedures prescribed in 5 CFR 1320.12. On August 9, 2012 (77 FR 47631), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0534, which is available for either public viewing online at either *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NSPS for Surface Coating of Plastic Parts for Business Machines (Renewal).

ICR Numbers: EPA ICR Number 1093.10, OMB Control Number 2060–0162.

ICR Status: This ICR is scheduled to expire on January 31, 2013. Under OMB regulations, the Agency may continue to either conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart TTT.

Owners or operators of the affected facilities must make an initial notification report, performance tests, periodic reports, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are also required semiannually.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 35 hours per response. ''Burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners and operators of facilities that apply surface coatings to plastic parts for use in the manufacture of business machines.

Estimated Number of Respondents: 10.

Frequency of Response: Quarterly and semiannually.

Estimated Total Annual Hour Burden: 979.

Estimated Total Annual Cost: $94,725, which includes $94,725 in labor costs, and neither capital/startup costs, nor operation and maintenance (O&M) costs.

Changes in the Estimates: There is an increase of one hour in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program change, but rather it is due to the fact that the current total of burden hours was rounded off to the next-highest whole number. There is an increase in costs for both the respondents and the Agency from the most recently approved ICR. The increase in burden cost is due to an increase in labor rates. This ICR uses updated labor rates from the Bureau of Labor Statistics to calculate burden costs.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–00817 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0502; FRL–9526–3]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Hospital/Medical/Infectious Waste Incinerators (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before February 15, 2013.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0502, to: (1) EPA online, using *www.regulations.gov* (our preferred method), or by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for

review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 9, 2012 (77 FR 47631), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0502, which is available for either public viewing online at either *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NSPS for Hospital/Medical/Infectious Waste Incinerators (Renewal).

ICR Numbers: EPA ICR Number 1730.09, OMB Control Number 2060–0363.

ICR Status: This ICR is scheduled to expire on January 31, 2013. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart Ec.

Owners or operators of the affected facilities must make an initial notification report, performance tests, periodic reports, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are also required semiannually.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 115 hours per response. ''Burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners and operators of hospital, medical or infectious waste incinerators.

Estimated Number of Respondents: 5.

Frequency of Response: Initially, occasionally, semiannually and annually.

Estimated Total Annual Hour Burden: 3,912.

Estimated Total Annual Cost: $664,375, which includes $378,826 in labor costs, $90,924 in capital/startup costs, and $194,625 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens; however, this increase is not due to any program changes. The change in the burden and cost estimates occurred because the revised standard has been in effect for more than three years and the requirements are different during initial compliance for new facilities, as compared to on-going compliance for existing facilities. The previous ICR reflected those burdens and costs associated with the initial activities for subject facilities. This includes purchasing monitoring equipment, conducting performance tests and establishing recordkeeping systems. This ICR reflects the on-going burden and costs for existing facilities. Activities for existing source include continuously monitoring of pollutants and the submission of semiannual reports. In addition, there are a number of new facilities that are in the initial compliance phase described above. The overall result is an increase in burden hours, labor costs, and O&M costs. Furthermore, a portion of the labor cost increase is a result of increased labor rates. This ICR uses updated labor rates from the Bureau of Labor Statistics to calculate burden costs.

Additionally, there is an adjustment decrease in capital costs in this ICR compared to the previous ICR. This is not due to any program changes. The previous ICR assumed all capital costs associated with monitoring were incurred during a single year; whereas this ICR calculates the average capital costs for new sources of each year that is covered under the ICR.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–00818 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0937; FRL–9374–8]

3-Decen-2-One; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Wisconsin Department of Agriculture, Trade, and Consumer Protection to use the pesticide 3-decen-2-one (CAS No. 10519–33–2) to treat up to 500,000 tons of potatoes with 3-decen-2-one to burn-off potato sprouts in storage facilities. The applicant proposes the use of a new chemical which has not been registered by the EPA. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before January 31, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2012–0937 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Amaris Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–9542; fax number: (703) 605–0781; email address: *johnson.amaris@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have a typical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the Administrator determines that emergency conditions exist which require the exemption. The Wisconsin Department of Agriculture, Trade and Consumer Protection has requested the EPA Administrator to issue a specific exemption for the use of 3-decen-2-one on potatoes in storage facilities to burn off already emerged sprouts. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that the 2012 growing season started 2–3 weeks early and was unseasonably warmer by 3–5 degrees Fahrenheit. This resulted in potatoes sprouting early in storage facilities, and thus the need to control the sprouting to prevent potential economic loss. Buyers can reject or mark down full loads of potatoes even if minor sprouting is observed. Currently, there are many stored potatoes with sprouts greater than 1 millimeter (mm) in Wisconsin. 3-decen-2-one is the best option for stored potatoes because it burns off existing sprouts, even those greater than 1 mm. The majority of alternatives do not burn off existing sprouts nor can they be used on sprouts greater than 1 mm. If the use of 3-decen-2-one is not permitted, the economic loss to the state of Wisconsin is estimated at 40% of the state's potato crop or up to 500,000 tons.

The applicant proposes to make no more than two applications of the chemical with at least 7 days between applications (retreatment interval), the maximum number of stored potatoes to be treated is 10,000,000 hundredweight (cwt) or 500,000 tons. The total amount of product is 16,406 gallons or 16,078 gallons of active ingredient, during the growing season from now through July 2013. The use of 3-decen-2-one is permissible in the following Wisconsin counties: Adams, Barron, Chippewa, Columbia, Green Lake, Iowa, Jefferson, Juneau, Marquette, Portage, Richland, Sauk, Shawano, Waushara, Waupaca, Wood, Langlade, and Oneida.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient) which has not been registered by EPA. The notice provides an opportunity for public comment on the application.

The Agency, will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Wisconsin Department of Agriculture, Trade and Consumer Protection.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: January 3, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–00730 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2005–0252; FRL–9375–9]

Iodomethane; Cancellation Order for Pesticide Registrations and Label Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellation, voluntarily requested by the registrant and accepted by the Agency, of products containing iodomethane, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a November 21, 2012 **Federal Register** Notice of Receipt of Request from the registrant listed in Table 3 of Unit II. to voluntarily cancel all these product registrations and to amend the technical/manufacturing-use label. These are the last products containing this pesticide registered for use in the United States. In the November 21, 2012 notice, EPA indicated that it would issue an order implementing the cancellations and amendment, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests. The Agency received one comment on the notice, but it did not merit further review of the requests. Further, the registrant did not withdraw their request. Accordingly, EPA hereby issues this order granting the requested cancellations and amendment. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations of the end-use product registration are effective December 31, 2012. The cancellation of the technical product is effective December 1, 2015. The amendment to the technical label is effective January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Andrea Mojica, Pesticide Re- Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–0122; fax number: (703) 308–8090; email address: *mojica.andrea@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2005–0252, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the agency taking?

This notice announces the cancellation(s) and label amendment of the products listed in Tables 1 and 2, as requested by the registrant of these products, which are registered under FIFRA section 3. These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1—IODOMETHANE PRODUCT CANCELLATIONS

EPA Registration No.	Product name
66330–43	Midas 98:2.
66330–44	Iodomethane Technical.
66330–57	Midas 50:50.
66330–58	Midas EC Bronze.
66330–59	Midas 33:67.
66330–60	Midas EC Gold.

TABLE 2—IODOMETHANE PRODUCT REGISTRATION AMENDMENTS

EPA Registration No.	Product name
66330–44	Iodomethane Technical.

Table 3 of this unit includes the name and address of record for the registrant of the products in Tables 1 and 2 of this unit.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS

EPA Company No.	Company name and address
66330	Arysta LifeScience North America, 15401 Weston Parkway, Suite 150, Cary, NC 27513.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received one comment in response to the November 21, 2012 **Federal Register** notice announcing the Agency's receipt of the request for voluntary cancellation of the products listed in Table 1of Unit 2, and the label amendment of the product listed in Table 2 of Unit II. The Pesticide Action Network International (PAN) expressed support for the proposed cancellations. However, PAN also requested that EPA prohibit the use of the iodemethane technical product in the U.S. to formulate products for export. In the November 21, 2012 notice, EPA referenced a Memorandum of Agreement (MOA) between the technical registrant for iodomethane and EPA. One provision of the MOA requires Arysta to voluntarily amend its technical product label to only allow sale and distribution for export purposes after January 1, 2013. Section 17 of FIFRA (7 U.S.C. 136o), and EPA regulations at 40 CFR part 168 Subpart D have specific requirements that apply to the export of unregistered pesticide, but these provisions do not provide EPA with authority to ban the export of pesticides registered under Section 3 of FIFRA, or cancelled pesticides. For these reasons, the Agency does not believe that the comment submitted by PAN merits further review or a denial of the requests for voluntary cancellation and a label amendment.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations and label amendment of

the iodomethane registrations identified in Tables 1 and 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1 and 2 of Unit II. are canceled and the product registration identified in Table 2 of Unit II. is amended. The effective date of the cancellation for the following products that are subject of this notice, EPA Registration Numbers 66330–43, 66330–57, 66330–58, 66330–59 and 66330–60, is December 31, 2012. The effective date of the cancellation for EPA Registration Number 66330–44 is December 1, 2015. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA. Within 30 days of the date of publication of this order, Arysta shall send the following documents by certified mail, return receipt requested, to every person who purchased any such product directly from Arysta since December 31, 2011; and to every retailer known to Arysta to have sold any end-use product since December 31, 2011: A letter that identifies or indicates:

1. The iodomethane product(s) that were purchased and the dates of such purchase.

2. That any distribution or sale of Arysta's end-use iodomethane products will be unlawful under FIFRA after December 31, 2012.

3. That Arysta's end-use iodomethane products in users' possession may not be used after December 31, 2012.

4. That after December 31, 2012, all remaining existing stocks of Arysta's iodomethane end-use products must be disposed of in accordance with all applicable state and Federal laws or returned to Arysta; and a hard copy of the actual cancellation order as published in the **Federal Register**.

V. What is the agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment on November 21, 2012 (77 FR 69840) (FRL–9370–2). The comment period closed on December 21, 2012.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

As of December 1, 2015, all sale and distribution of existing stocks of Arysta's iodomethane technical/manufacturing-use product, EPA Reg. No. 66330–44, by Arysta shall be prohibited unless the sale or distribution is for proper disposal or is solely for purposes of export consistent with the requirements of section 17 of FIFRA.

As of December 31, 2012, Arysta is prohibited from distributing or selling existing stocks of end-use products, EPA Registration Nos. 66330–43, 66330–57, 66330–58, 66330–59 and 66330–60 unless the sale or distribution is for proper disposal, or is solely for export consistent with the requirements of FIFRA section 17; persons other than Arysta are prohibited from distributing or selling existing stocks of Arysta's end-use products, EPA Registration Number 66330–43, 66330–57, 66330–58, 66330–59 and 66330–60, unless the sale or distribution is for proper disposal, return to Arysta, or is intended solely for export consistent with the requirements of FIFRA section 17; and no person may use any existing stocks of any of Arysta's end-use products EPA Registration Numbers. 66330–43, 66330–57, 66330–58, 66330–59 and 66330–60.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: December 28, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2013–00732 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0906; FRL–9374–4]

Pesticides; Draft Guidance for Pesticide Registrants on Web-Distributed Labeling for Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Agency is announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) titled ''Web-Distributed Labeling for Pesticide Products.'' PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular draft PR Notice provides guidance concerning the process by which registrants can make legally valid versions of pesticide labeling available through the Internet. Web-distributed labeling would allow users to retrieve a streamlined version of the pesticide product labeling, containing the directions for use and necessary information related to the user's specific state and intended site of use. Shorter, relevant labeling could be clearer and easier for the user to understand, improving compliance with pesticide labeling requirements and thereby protecting human health and the environment from unintentional misuse of pesticides. Web-distributed labeling would also allow for more rapid updates to pesticide labeling, meaning risk mitigation measures and new uses can reach the user more quickly than under the current paper-based system.

DATES: Comments must be received on or before April 16, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2012–0906, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michelle Arling, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–5891; fax number: (703) 308–2962; email address: *arling.michelle@epa.gov@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, although this action may be of particular interest to those persons who register and use pesticide products and to state regulators of pesticide products. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Specific Areas for Comment.* EPA has identified questions about the PR Notice on which the Agency would like to receive specific input from commenters. These questions and topic areas are presented below.

i. Would an appendix with sample master labeling and web-distributed labeling rendered output assist in understanding the PR Notice and how to follow the recommendations in the PR Notice?

ii. The PR Notice suggests that it ''is targeted towards pesticide products marketed primarily to applicators for use in the course of commercial activity.'' Please comment on the scope of coverage. Should the Agency expand or contract the targeted products? Are there alternate ways to describe the targeted products?

iii. Should the Agency consider combining the released for shipment date and the unique identifier into a single alpha-numeric combination? If so, why? Please provide suggested definitions for any proposed alternative.

iv. Should the released for shipment date and unique identifier have a standard location on the container or pesticide labeling? If so, where? If not, why?

v. Should EPA approve web-distributed labeling for one or some, but not all, uses listed on a product's labeling? If so, how would users know that no web-distributed labeling was available for their intended use?

vi. Should EPA consider only accepting WDL submissions to the Agency for review as electronic files?

vii. Please provide comments on the web-distributed labeling statements and their recommended location. Should they be located at the beginning of the directions for use? Should they be a separate section on the labeling, similar to the Agricultural Use Box that conveys information about the Worker Protection Standard? Would either approach make the user more likely to read and comply with the information?

viii. Please provide comments on the minimum functionality discussed in Unit IV. ix. Are the proposed standards reasonable? If not, please suggest alternative guidelines.

x. Please provide any other comments on the PR Notice. If you disagree with or do not understand any aspect of the PR Notice, please describe the area and an alternative that incorporates your suggestions.

C. How can I get copies of this document and other related information?

A copy of the draft PR notice is available in the docket under docket identification (ID) number EPA–HQ–OPP–2012–0906.

II. What guidance does this PR notice provide?

A. Background

Since 2007, the Agency has been exploring the feasibility and advisability of allowing registrants to make legally enforceable pesticide product labeling available to users via the Internet, an initiative referred to as ''web-distributed labeling'' (WDL). At the end of 2010, EPA initiated a ''user acceptance pilot.'' (75 FR 51058, August 18, 2010; EPA–HQ–OPP–2010–0632) The user acceptance pilot involved a simulation of a WDL Web site that users could visit and on which they could provide feedback. The user acceptance pilot did not involve any changes to existing pesticide labeling on containers or legally valid electronic versions of pesticide labeling. EPA also published a **Federal Register** notice which outlined EPA's positions on issues related to WDL and sought comment on a number of these issues. (75 FR 82011, December 29, 2010; EPA–HQ–OPP–2010–0648).

Based on its review of the comments and other feedback received from the **Federal Register** notice and the user acceptance pilot, EPA is proposing a voluntary approach to WDL that would allow registrants to distribute pesticide products with labeling that refers the user to the Web site from which the user may download legally valid, enforceable labeling. The container would still be accompanied by a physical copy of the EPA-accepted labeling sufficient for the correct use of the product, but a user could access the most current version of the state- and site-specific labeling from a Web site identified on the container label. Offering WDL while retaining the full labeling on or accompanying pesticide containers would allow users, registrants, and EPA to acquire a better understanding of the strengths and limitations of WDL and possibly serve as a transition to a system which relies more heavily on the Internet and other technologies to provide users with legally enforceable labeling. For example, registrants could determine whether specific types of products would be better suited to WDL and users could evaluate the relative benefit

of WDL versus the current pesticide product labeling.

As considered by EPA, WDL would make available via the Internet site- and state-specific use directions for pesticide products as downloadable electronic files. To access this labeling, a user would visit the Web site identified on the pesticide label, enter information identifying the product, and select the intended state and use site. The Web site would return a streamlined version of the pesticide labeling containing the language applicable to all uses of the product, such as hazard statement and first aid, and the relevant state/site specific directions for use (e.g., application to cranberries in Maine). Sufficient labeling for the correct use of the product would still be available with the pesticide either on the container label or in accompanying material.

B. Overview of PR Notice

This PR Notice provides guidance about how EPA intends to implement WDL under this system. First, the PR Notice defines terms used related to WDL in this notice. It includes suggested language that registrants can use on the labeling affixed to or accompanying the pesticide container to reference the WDL portion of labeling. It recommends content, function, and security for the Web site associated with a product's WDL. Finally, the PR Notice suggests a process by which registrants can request that a product's labeling include WDL and outlines what information EPA expects to receive.

III. Do PR notices contain binding requirements?

The PR Notice discussed in this notice is intended to provide guidance to EPA personnel and decisionmakers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: January 3, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2013–00560 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9770–5]

Office of Environmental Information; Announcement of Availability and Comment Period for the Draft Quality Standard for Environmental Data Collection, Production, and Use by Non-EPA (External) Organizations and Two Associated QA Handbooks; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability & request for comment; extension of comment period and correction.

SUMMARY: The Environmental Protection Agency published a document in the **Federal Register** of December 26, 2012, concerning request for comments for the Draft Quality Standard for Environmental Data Collection, Production, and Use by Non-EPA (External) Organizations and two associated QA Handbooks. The notice of availability is being extended to a 45 day review and comment period and the document contained incorrect Web site links in the footnotes.

DATES: Comments must be submitted on or before February 11, 2013.

FOR FURTHER INFORMATION CONTACT: John Warren, Environmental Protection Agency; 1200 Pennsylvania Avenue, MC 2811R; Washington, DC 20460; Phone: 202–564–6876.

Correction

In the **Federal Register** of December 26, 2012 in FRL 9764–3, page 76035, second column correct line after **SUMMARY** to read:

''**SUMMARY**: Notice of availability for a 45 day review and comment period is hereby given for the draft Quality Standard for Environmental Data Collection, Production, and Use by Non-EPA (External) Organizations and two associated draft QA Handbooks; 1) draft Handbook for Preparing Quality Management Plans (QMPs) and 2) draft Handbook for Preparing Quality Assurance (QA) Project Plans (QAPPs).''

In the **Federal Register** of December 26, 2012 in FRL 9764–3, on page 76036, at the bottom of the first column; correct the Web site references for footnotes one and two to read:

[1] *http://www.epa.gov/irmpoli8/policies/21050.pdf*

[2] *http://www.epa.gov/irmpoli8/policies/21060.pdf*

Monica D. Jones,

Director, Quality Staff.

[FR Doc. 2013–00836 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0019; FRL–9375–2]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions were granted during the period July 1, 2012 to September 30, 2012 to control unforeseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption for the name of a contact person. The following information applies to all contact persons: Team Leader, Emergency Response Team, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8050.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the emergency exemption.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0019, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. Background

EPA has granted emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific.

Under FIFRA section 18, EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A ''specific exemption'' authorizes use of a pesticide against specific pests on a limited acreage in a particular State. Most emergency exemptions are specific exemptions.

2. ''Quarantine'' and ''public health'' exemptions are emergency exemptions issued for quarantine or public health purposes. These are rarely requested.

3. A ''crisis exemption'' is initiated by a State or Federal agency (and is confirmed by EPA) when there is insufficient time to request and obtain EPA permission for use of a pesticide in an emergency.

EPA may deny an emergency exemption: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in ''a reasonable certainty of no harm'' to human health, including exposure of residues of the pesticide to infants and children.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the ''reasonable certainty of no harm standard'' of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption, the type of exemption, the pesticide authorized and the pests, the crop or use for which authorized, number of acres (if applicable), and the duration of the exemption. EPA also gives the **Federal Register** citation for the time-limited tolerance, if any.

III. Emergency Exemptions

A. U.S. States and Territories

California

Department of Pesticide Regulation

Specific Exemption: EPA Authorized the use of spirotetramat on dry bulb onions to control thrips; July 12, 2012 to September 15, 2012. *Contact:* Keri Grinstead.

Delaware

Department of Agriculture

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

Florida

Department of Agriculture and Consumer Services

Specific Exemption: EPA Authorized the use of spirotetramat on watercress to control melon/cotton aphids; July 27, 2012 to July 27, 2013. *Contact:* Keri Grinstead.

Specific Exemption: EPA authorized the use of streptomycin sulfate on grapefruit to control citrus canker; September 14, 2012 to September 1, 2013. As allowed by 40 CFR 166.24, the Agency determined that publication of a notice of receipt was appropriate since the use is for expansion of an antibiotic, and of potential public interest. A notice of receipt published in the **Federal Register** on November 9, 2011 (76 FR 217) (FRL–9325–8), to allow for a public comment period which ended on November 24, 2011. No substantial comments were received. The rationale for emergency approval of this use is that no suitable materials are available to control citrus canker in grapefruit and significant economic losses will occur if this disease is not controlled. *Contact:* Andrea Conrath.

Illinois

Department of Agriculture

Specific exemption: EPA authorized the use of hop beta acids in beehives to control varroa mite; September 5, 2012 to December 31, 2012. *Contact:* Stacey Groce.

Louisiana

Department of Agriculture and Forestry

Crisis Exemption: EPA concurred with Louisiana on the crisis use of imidacloprid on sugarcane to control West Indian Cane Fly; August 7, 2012 to August 22, 2012. *Contact:* Tawanda Maignan.

Maine

Department of Agriculture, Food and Rural Resources

Crisis Exemption: EPA concurred with Maine on the crisis use of malathion on blueberries to control spotted winged drosophila; August 13, 2012 to August 28, 2012. *Contact:* Debra Rate.

Specific exemption: EPA authorized the use of hop beta acids in beehives to control varroa mite; August 3, 2012 to December 31, 2012. *Contact:* Stacey Groce.

Maryland

Department of Agriculture

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

Michigan

Department of Agriculture and Rural Development

Crisis Exemption: EPA concurred with Michigan on the crisis use of malathion on blueberries to control spotted winged drosophila; July 6, 2012. *Contact:* Debra Rate.

Specific exemption: EPA authorized the use of malathion on blueberries to control spotted wing drosophila; September 27, 2012 to September 30, 2012. *Contact:* Debra Rate.

New Jersey

Department of Environmental Protection

Crisis Exemption: EPA concurred with New Jersey on the crisis use of malathion on blueberries to control spotted wing drosophila; July 16, 2012 to July 30, 2012. *Contact:* Tawanda Maignan.

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

Specific Exemption: EPA authorized the use of dinotefuran on stone fruit and pome fruit to control brown marmorated

stink bug; July 11, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

New Mexico

Department of Agriculture

Specific Exemption: EPA authorized the use of spirotetramat on dry bulb onions to control thrips; July 9, 2012 to October 31, 2012. *Contact:* Keri Grinstead.

North Carolina

Department of Agriculture and Consumer Services

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

North Dakota

Department of Agriculture

Specific exemption: EPA authorized the use of hop beta acids in beehives to control varroa mite; July 18, 2012 to December 31, 2012. *Contact:* Stacey Groce.

Oregon

Department of Agriculture

Specific Exemption: EPA authorized the use of fipronil on turnip and rutabaga to control cabbage maggot; July 20, 2012 to September 30, 2012. In accordance with 40 CFR 166.24, a notice of receipt published in the **Federal Register** on May 1, 2012 (77 FR 84) (FRL– 9344–3), to allow for public comment since the request proposed a use which is IR–4-supported, has been requested in 5 or more previous years, and a petition for tolerance has not been submitted to the Agency. The public comment period ended on May 16, 2012. No substantial comments were received. The rationale for emergency approval of this use is that no suitable insecticides are available to control the cabbage maggot in turnip and rutabaga production and significant economic losses will occur if this pest is not controlled. *Contact:* Andrea Conrath.

Pennsylvania

Department of Agriculture

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

Tennessee

Department of Agriculture and Regulatory Services

Specific Exemption: EPA authorized the use of spirotetramat on watercress to control melon/cotton aphids; July 27, 2013 to July 27, 2013. *Contact:* Keri Grinstead.

Virginia

Department of Agriculture and Consumer Services

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

West Virginia

Department of Agriculture

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach, and nectarine to control brown marmorated stink bug; July 20, 2012 to October 15, 2012. *Contact:* Andrea Conrath.

B. Federal Departments and Agencies

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)

Quarantine Exemption: EPA authorized the use of sodium hydroxide on clean, hard, non-porous areas potentially exposed to prions. September 12, 2012 to September 12, 2015; *Contact:* Keri Grinstead.

Quarantine Exemption: EPA authorized the use of sodium hypochlorite on clean, hard, non-porous areas potentially exposed to prions. September 12, 2012 to September 12, 2015; *Contact:* Keri Grinstead.

National Aeronautics and Space Administration (NASA)

Specific exemption: EPA authorized the use of ortho-phthalaldehyde (OPA) immobilized to a porous resin to treat the International Space Station internal active thermal control system (IATCS) coolant to control micro-organisms; July 13, 2012 to July 12, 2013. This request was granted because no registered alternatives met the criteria required for this use as well as OPA. Since the request proposed the use of a new, unregistered chemical, a notice of receipt published in the **Federal Register** on August 17, 2012 (77 FR 49793) (FRL–9358–4). *Contact:* Debra Rate.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: January 7, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–00841 Filed 1–15–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2012–0390; FRL–9375–6]

Notice of Receipt of Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing an active ingredient not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before February 15, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the EPA File Symbol of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone, email, or mail. Mail correspondence to the Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA has received applications to register pesticide products containing an active ingredient not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under the Agency's public participation process for registration actions, there will be an additional opportunity for a 30–day public comment period on the proposed decision. Please see the Agency's public participation Web site for additional information on this process (*http://www.epa.gov/pesticides/regulating/registration-public-involvement.html*). EPA received the following applications to register pesticide products containing an active ingredient not included in any currently registered products:

1. *EPA File Symbol:* 71840–RL. *Docket ID Number:* EPA–HQ–OPP–2012–0962. *Applicant:* Becker Underwood, Inc., 801 Dayton Ave., P.O. Box 667, Ames, IA 50010. *Active Ingredient: Trichoderma fertile* strain JM41R at 96.0%. *Product Type:* Fungicide. *Proposed Use:* Manufacturing use. *Contact:* Jeannine Kausch, (703) 347–8920, email address: *kausch.jeannine@epa.gov.*

2. *EPA File Symbol:* 71840–RU. *Docket ID Number:* EPA–HQ–OPP–2012–0962. *Applicant:* Becker Underwood, Inc., 801 Dayton Ave., P.O. Box 667, Ames, IA 50010. *Active Ingredient: Trichoderma fertile* strain JM41R at 7.7%. *Proposed Use:* For control of diseases (e.g., *Sclerotinia* and *Fusarium*) found in soil and growing media that is used in greenhouses and nurseries. *Contact:* Jeannine Kausch, (703) 347–8920, email address: *kausch.jeannine@epa.gov.*

List of Subjects

Environmental protection, Pesticides and pest.

Dated: January 8, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–00711 Filed 1–14–13; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2013–0103]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB Review and Comments Request.

Form Title: Application for Long Term Loan or Guarantee (EIB 95–10).

SUMMARY: Export-Import (Ex-Im) Bank is requesting an emergency approval for form EIB 95–10 Application for Long Term Loan or Guarantee, OMB 3048–0013, because the Export Import Bank Reauthorization Act of 2012 has placed additional reporting requirements on the Bank.

By neutralizing the effect of export credit insurance and guarantees offered by foreign governments and by absorbing credit risks that the private section will not accept, Ex-Im Bank enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. This collection of information is necessary, pursuant to 12 USC Sec. 635 (a) (1), to determine eligibility of the applicant for Ex-Im Bank Assistance.

The collection will provide information needed to determine compliance and creditworthiness for transaction requests submitted to Ex-Im Bank under its long-term guarantee and direct loan programs. The form is currently used to make a credit decision on approximately 85 export transactions per year in divisions dealing with aircraft, structured finance, and trade finance.

The application can be viewed at *www.exim.gov/pub/pending/eib95-10.pdf.*

DATES: Comments should be received on or before March 18, 2013 to be assured of consideration.

ADDRESSES: Comments maybe submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Michele Kuester, Export Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 95–10 Application for Long Term Loan or Guarantee.

OMB Number: 3048–0013.

Type of Review: Regular.

Need and Use: The information collected will provide information needed to determine compliance and creditworthiness for transaction requests submitted to the Export Import Bank under its long term guarantee and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 84.

Estimated Time per Respondent: 1.5 hours.

Government Annual Burden Hours: 2,100.

Frequency of Reporting or Use: Yearly.

Total Cost to the Government: $81,312.

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2013–00766 Filed 1–15–13; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011733–030.

Title: Common Ocean Carrier Platform Agreement.

Parties: A.P. Moller-Maersk A/S; American President Lines, Ltd., APL Co., PTE Ltd.; CMA CGM; Hamburg-Süd; Hapag-Lloyd AG; Mediterranean Shipping Company S.A.; and United Arab Shipping Company (S.A.G.) as shareholder parties, and Alianca Navegacao e Logistica Ltda.; China Shipping Container Lines Company Limited; Compania Sud Americana de Vapores, S.A.; Companhia Libra de Navegacao; COSCO Container Lines Co., Ltd.; Emirates Shipping Lines; Evergreen Line Joint Service Agreement; Gold Star Line, Ltd.; Hanjin Shipping Co., Ltd.; Hyundai Merchant Marine Co. Ltd; Kawasaki Kisen Kaisha, Ltd.; MISC Berhad; Mitsui O.S.K. lines Ltd.; Nippon Yusen Kaisha; Norasia Container Lines Limited; Tasman Orient Line C.V. and Zim Integrated Shipping as non-shareholder parties.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment removes Safmarine Container Lines N.V. as a party and adds Safmarine MPV N.V. as a party to the agreement.

Agreement No.: 011961–013.

Title: The Maritime Credit Agreement.

Parties Alianca Navegacao e Logistica Ltda. & Cia.; A.P. Moller-Maersk A/S trading under the name of Maersk Line; China Shipping Container Lines Co., Ltd.; CMA CGM S.A.; Companhia Libra de Navegacao; Compania Libra de Navegacion Uruguay S.A.; Compania Sud Americana de Vapores, S.A.; COSCO Container Lines Company Limited; Dole Ocean Cargo Express; Hamburg-Süd; Hyundai Merchant Marine Co., Ltd.; Independent Container Line Ltd.; Kawasaki Kisen Kaisha, Ltd.; Nippon Yusen Kaisha; Norasia Container Lines Limited; United Arab Shipping Company (S.A.G.); Wallenius Wilhelmsen Logistics AS; YangMing Marine Transport Corp.; Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment removes Safmarine Container Lines N.V. as party to the Agreement.

Dated: January 11, 2013.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–00834 Filed 1–15–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Concepts in Freight, Inc. (NVO & OFF), 10813 NW 30th Street, Doral, FL 33172. Officers: Fadi Aftimos, Vice President (QI) Asma Aftimos, President. Application Type: QI Change.

Katoen Natie Tank Operations, Inc. (NVO & OFF), 1805 Turning Basin Drive, Suite 100A, Houston, TX 77029. Officers: Frank Vingerhoets, Director (QI), Suzanna Van Goethem, Director. Application Type: QI Change.

Interglobal Shipping, LLC (OFF), 14900 Woodham Drive, Suite A–150, Houston, TX 77073. Officers: Afsaneh Saei Oskoei, Managing Member (QI) Prince Eti, Member Application Type: New OFF License.

MGK International, Inc. (OFF), 13 Roszel Road, Suite C 201, Princeton, NJ 08540. Officer: Hitendra Jain, President (QI), Application Type: New OFF License.

Oceans Consolidators Inc. (NVO & OFF), 10975 NW 29th Street, Miami, FL 33172. Officers: Carlos J. Bengochea, President (QI), Olga R. Bengochea, Vice President. Application Type: Add OFF Service.

Perimeter International dba Perimeter Logistics (NVO & OFF), 2700 Story Road West, Irving, TX 75038. Officers: Beau Lamothe, Treasurer (QI) Merry Lyn Lamothe, President. Application Type: New NVO & OFF License.

Dated: January 11, 2013.

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–00825 Filed 1–15–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Rescission of Order of Revocation

The Commission gives notice that it has rescinded its Order revoking the following license pursuant to section 40901 of the Shipping Act of 1984 (46 U.S.C. 40101).

License No.: 003135F.

Name: N & N Safeway Shipping Company.

Address: 871 E. Artesia Blvd., Carson, CA 90746.

Order Published: December 6, 2012 (Volume 77, No. 235, Pg. 72863)

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2013–00826 Filed 1–15–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 013253N.
Name: Total Service Line Corporation dba Total Shipping Line Corp.
Address: 12140 East Artestia Blvd., Suite 208, Artesia, CA 90701.
Date Revoked: November 11, 2012.
Reason: Failed to maintain a valid bond.

License No.: 017580N.
Name: E-Trans Logistic Services, Inc.
Address: 17595 Almahurst Road, Suite 211, City of Industry, CA 91748.
Date Revoked: November 18, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020933N.
Name: Surexpress, Inc.
Address: 7040 Motz Street, Paramount, CA 90723.
Date Revoked: November 5, 2012.
Reason: Voluntary Surrender of License.

License No.: 021296NF.
Name: ITW International, Inc.
Address: 2889 Plaza Del Amo, #312, Torrance, CA 90503.
Date Revoked: November 5, 2012.
Reason: Voluntary Surrender of License.

Vern W. Hill,
Director, Bureau of Certification and Licensing.

[FR Doc. 2013–00832 Filed 1–15–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 31, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Robert M. Wrobel Trust, Mr. Robert Wrobel, Glencoe, Illinois, as Trustee; the Debra Wrobel Trust, Debra Wrobel, Glencoe, Illinois, as Trustee; three related Wrobel Family Trusts, Debra Wrobel, Glencoe, Illinois, as Trustee; and Dr. Jack Havdala,* Jonesboro, Arkansas; as a group acting in concert, to acquire at least 25 percent of the voting shares of Amalgamated Investments Company, and thereby indirectly acquire voting shares of Amalgamated Bank of Chicago, both in Chicago, Illinois.

2. *Stanley Dickson, Jr., Gross Pointe Park, Michigan, as an individual, and the group consisting of Stanley Dickson, Jr., Gross Pointe Park, Michigan; Steven Dickson, Rancho Santa Fe, California; Kathryn J. Dickson, Howell, Michigan; and Riddle Limited Partnership,* Howell, Michigan; to acquire voting shares of FNBH Bancorp, Inc., and thereby indirectly acquire voting shares of First National Bank in Howell, both in Howell, Michigan.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Dalene M. Selko,* Meade, Nebraska; to acquire voting shares of Selko Banco, Inc., and thereby indirectly acquire voting shares of Bank of Mead, both in Mead, Nebraska.

Board of Governors of the Federal Reserve System, January 11, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013–00769 Filed 1–15–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 11, 2013.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. *The Adirondack Trust Company Employee Stock Ownership Trust,* Saratoga Springs, New York; to acquire 50 additional shares of 473 Broadway Holding Corporation, and 2,000 additional shares of The Adirondack Trust Company, both in Saratoga Springs, New York.

Board of Governors of the Federal Reserve System, January 11, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013–00768 Filed 1–15–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 112 3195]

Filiquarian Publishing, LLC; Choice Level, LLC; and Joshua Linsk; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 11, 2013.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/filiquarianconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Filiquarian, File No. 112 3195'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/filiquarianconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jessica Lyon (202–326–2344), FTC, Bureau of Consumer Protection, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 10, 2013), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 11, 2013. Write ''Filiquarian, File No. 112 3195'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver' license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which * * * is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/filiquarianconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Filiquarian, File No. 112 3195'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 11, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Filiquarian Publishing, LLC; Choice Level, LLC; and Joshua Linsk, individually, and as an officer of the companies.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The Commission's proposed administrative complaint alleges that the companies were operating as consumer reporting agencies without any procedures or policies in place to comply with the Fair Credit Reporting Act (''FCRA'').

The respondents sold background screening reports containing criminal records through mobile applications (''apps'') available in the iTunes and Google Android store (now GooglePlay) and through a Web site. Filiquarian developed and marketed apps that sold for $0.99 each and allowed purchasers to conduct unlimited searches of criminal history information within a specific geographic area, such as a state or county. Each app included an express representation that purchasers could use the reports for employment purposes. Choice Level provided the underlying records accessed by purchasers of the Filiquarian apps. Joshua Linsk is the owner and sole officer of Filiquarian and Choice Level. During all times material to this complaint, Linsk, individually or in concert with others, formulated, directed, or controlled the policies, acts, or practices of the companies.

According to the complaint, despite Filiquarian clearly promoting its background reports for use in employment screening, both Filiquarian and Choice Level included disclaimers in their terms and conditions stating that their reports were not to be considered a screening product for insurance, employment, or credit, and that they were not compliant with the FCRA. Such disclaimers contradicted and failed to counteract the express representations made in Filiquarian's advertising, urging the use of the reports to screen potential employees. Marketing and selling background screening reports to potential employers without implementing any of the accuracy or dispute safeguards required by the FCRA potentially exposes a large number of consumers to harm to their reputations and employment prospects.

The complaint alleges that the reports produced by respondents were consumer reports under the FCRA and that respondents lacked any policies or procedures to comply with the FCRA. Specifically, the complaint alleges that respondents failed to adhere to three key requirements of the FCRA: to maintain reasonable procedures to verify who their users are and that the information would be used for a permissible purpose; to ensure that the information they provided in consumer reports was accurate; and to provide notices to users and to those who furnished proposed respondents with information that was included in consumer reports. The complaint further alleges that by their violations of the FCRA, as stated above, proposed respondents have engaged in unfair and deceptive acts and practices, in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. 45(a).

The proposed consent order contains provisions designed to prevent the respondents from engaging in the future in practices similar to those alleged in the complaint.

Part I of the order includes injunctive relief requiring respondents to comply with the relevant provisions of the FCRA. Parts II through VI are reporting and compliance provisions. Part II requires respondents to retain documents relating to their compliance with the order for a five-year period. Part III requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part IV ensures notification to the FTC of changes in corporate status. Part V mandates that respondents submit a compliance report to the FTC within 60 days, and periodically thereafter as requested. Part VI is a provision ''sunsetting'' the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Richard C. Donohue,

Acting Secretary.

[FR Doc. 2013–00744 Filed 1–15–13; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 121–0120]

Motorola Mobility LLC and Google Inc.; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; correction.

SUMMARY: The Federal Trade Commission published a document in the **Federal Register** of January 11, 2013, requesting public comments on an analysis of proposed consent order to aid public comment. The document inadvertently did not include the Statement of the Commission. This document contains the Statement of the Commission.

FOR FURTHER INFORMATION CONTACT: Richard Feinstein or Pete Levitas (202–326–2555), FTC, Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

Correction

In the **Federal Register** of January 11, 2013, in FR Doc. 2013–00465, on page 2402, the third column, second paragraph (after ''Richard C. Donohue, Acting Secretary,'' but before the ''Statement of Commissioner Rosch,'') insert the following Statement of the Commission:

Statement of the Federal Trade Commission

The Federal Trade Commission has today voted to issue for public comment a Complaint and Order against Google Inc. (''Google'') designed to remedy Google's allegedly anticompetitive conduct resulting from breaches by Google and its subsidiary Motorola Mobility, Inc. (''Motorola'') of Motorola's commitments to license standard-essential patents (''SEPs'') on terms that are fair, reasonable and non-discriminatory (''FRAND'').[1] The Complaint alleges that, before its acquisition by Google, Motorola reneged on a licensing commitment made to several standard-setting bodies to license its standard-essential patents relating to smartphones, tablet computers, and video game systems on FRAND terms by seeking injunctions against willing licensees of those SEPs.[2] This conduct tended to impair competition in the market for these important electronic devices—products that over half of Americans own and use daily, including iPhones, iPads and Xboxes. After purchasing Motorola for $12.5 billion in June 2012, Google continued Motorola's conduct. These actions constitute unfair methods of competition, as well as unfair acts and practices, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45.

Google's settlement with the Commission requires Google to withdraw its claims for injunctive relief on FRAND-encumbered SEPs around the world, and to offer a FRAND license to any company that wants to license Google's SEPs in the future. If accepted by the Commission, the Proposed Order may set a template for the resolution of SEP licensing disputes across many industries, and reduce the costly and inefficient need for companies to amass patents for purely defensive purposes in industries where standard-compliant products are the norm.

The Commission has a long history of using its enforcement authority to safeguard the integrity of the standard-setting process.[3] Standard setting can deliver substantial benefits to American consumers, promoting innovation, competition, and consumer choice. But standard setting often supplants the competitive process with the collective decision-making of competitors, requiring that we be vigilant in protecting the integrity of the standard-setting process.[4] Today's Commission

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[1] The licensing obligation in this matter was a FRAND obligation, although RAND (reasonable and non-discriminatory) licensing obligations raise similar issues.

[2] Commissioners Rosch and Ohlhausen do not join this Statement (with Commissioner Ohlhausen voting against the consent agreement) and have issued separate statements expressing their views.

[3] *See In re Dell Computer Corp.,* 121 F.T.C. 616 (1996); *In re Union Oil Company of California,* 2004 FTC LEXIS 115 (July 7, 2004); *In re Rambus, Inc.,* Dkt. No. 9302, 2006 FTC LEXIS 101 (Aug. 20, 2006), *rev'd, Rambus Inc.* v. *F.T.C.,* 522 F.3d 456 (DC Cir. 2008); *In re Negotiated Data Solutions LLC,* FTC File No. 051–0094, Decision and Order (Jan. 23, 2008), *available at http://www.ftc.gov/os/caselist/0510094/080122do.pdf; In re Robert Bosch GmbH,* FTC File N. 121–0081, Decision and Order (Nov. 26, 2012), *available at http://www.ftc.gov/os/caselist/1210081/121126boschdo.pdf.*

[4] *See, e.g., Allied Tube & Conduit Corp.* v. *Indian Head, Inc.,* 486 U.S. 492, 500–01 (1988) (noting that

Continued

action helps ensure consumers will continue to see the benefits of competition and innovation in important technology markets.

We previously explained in the Commission's unanimous filings before the United States International Trade Commission in June 2012 that the threat of injunctive relief ''in matters involving RAND-encumbered SEPs, where infringement is based on implementation of standardized technology, has the potential to cause substantial harm to U.S. competition, consumers and innovation.'' [5] The threat of an injunction allows a SEP holder to demand and realize royalty payments reflecting the investments firms make to develop and implement the standard, rather than the economic value of the technology itself.[6] In addition to harming incentives for the development of standard-compliant products, the threat of an injunction can also lead to excessive royalties that may be passed along to consumers in the form of higher prices. Alternatively, an injunction or exclusion order could ban the sale of important consumer products entirely. This type of ''patent ambush'' harms competition and consumers and is rightly condemned by the Commission.[7]

We take this action pursuant to the Commission's authority under Section 5 to prohibit unfair methods of competition, which both Congress and the Supreme Court have expressly deemed to extend beyond the Sherman Act.[8] A stand-alone Section 5 unfair methods of competition claim allows the Commission to protect consumers and the standard-setting process while minimizing the often burdensome combination of class actions and treble damages associated with private antitrust enforcement. In a society that all of us recognize is overly litigious, the judicious use of Section 5 is a sensible and practical way for the Commission to bring problematic conduct to a halt. [9]

For these reasons, we respectfully disagree with the view of Commissioners Rosch and Ohlhausen that the conduct we challenge here, and the similar acts we challenged in *Bosch,* represent an undisciplined or unwarranted application of our unfair methods of competition authority. As we have previously explained, we believe that a breach of a FRAND commitment in the context of standard setting poses serious risks to the standard-setting process, competition, and consumers.[10] Where opportunistic behavior of the sort involved here (and in *Bosch*) harms, or threatens to harm, competition, the competitive process, and consumers, Commission intervention is justified. Accordingly, our colleagues' contention that we are applying our unfair methods of competition authority without regard for limiting principles is simply wrong. In fact, we note that our action is plainly consistent with several principles identified by Commissioner Rosch as justifying Commission action under Section 5.[11]

''private standard-setting associations have traditionally been objects of antitrust scrutiny'' because of their potential use as a means for anticompetitive agreements among competitors).

[5] Third Party United States Federal Trade Commission's Statement on the Public Interest filed on June 6, 2012 in *In re Certain Wireless Communication Devices, Portable Music & Data Processing Devices, Computers and Components Thereof,* Inv. No. 337–TA–745, *available at www.ftc.gov/os/2012/06/1206ftcwirelesscom.pdf* and in *In re Certain Gaming and Entertainment\ Consoles, Related Software, and Components Thereof,* Inv. No. 337–TA–752, *available at http://www.ftc.gov/os/2012/06/1206ftcgamingconsole.pdf.*

[6] *Id.* at 3–4 (''[A] royalty negotiation that occurs under threat of an exclusion order may be weighted heavily in favor of the patentee in a way that is in tension with the RAND commitment. High switching costs combined with the threat of an exclusion order could allow a patentee to obtain unreasonable licensing terms despite its RAND commitment, not because its invention is valuable, but because implementers are locked in to practicing the standard. The resulting imbalance between the value of patented technology and the rewards for innovation may be especially acute where the exclusion order is based on a patent covering a small component of a complex multicomponent product. In these ways, the threat of an exclusion order may allow the holder of a RAND-encumbered SEP to realize royalty rates that reflect patent hold-up, rather than the value of the patent relative to alternatives, which could raise prices to consumers while undermining the standard setting process.'').

[7] A number of courts have recognized the tension between Google's FRAND commitments and seeking injunctive relief. *See, e.g., Microsoft Corp.* v. *Motorola, Inc.,* 696 F.3d 872, 885 (9th Cir. 2012) (''Implicit in such a sweeping promise is, at least arguably, a guarantee that the patent-holder will not take steps to keep would-be users from using the patented material, such as seeking an injunction, but will instead proffer licenses consistent with the commitment made.''); *Apple, Inc.* v. *Motorola, Inc.,* No. 1:11-cv-08540, 2012 U.S. Dist. LEXIS 89960, at *45 (N.D. Ill. June 22, 2012) (Posner, J., sitting by designation) (''I don't see how, given FRAND, I would be justified in enjoining Apple from infringing the '898 [patent] unless Apple refuses to pay a royalty that meets the FRAND requirement. By committing to license its patents on FRAND terms, Motorola committed to license the '898 to anyone willing to pay a FRAND royalty and thus implicitly acknowledged that a royalty is adequate compensation for a license to use that patent. How could it do otherwise?'').

[8] *See, e.g., F.T.C.* v. *R.F. Keppel & Bros., Inc.,* 291 U.S. 304, 310–313 (1934); *F.T.C.* v. *Cement Inst.,* 333 U.S. 683, 693 & n.6 (1948); *F.T.C.* v. *Sperry & Hutchinson Co.,* 405 U.S. 233, 241–244 (1972).

[9] Chairman Leibowitz and Commissioner Brill support an unfair acts claim as well as an unfair methods claim. They have a reason to believe that seeking injunctions on FRAND-encumbered SEPs is likely to cause substantial harm to end-use consumers and, because FRAND commitments made to a standard-setting body often induce industry-wide lock-in and eliminate alternative technologies, this harm may not be reasonably avoided by consumers. Google's threat of injunctions would likely increase costs to consumers because manufacturers using Google's SEPs would be forced, by the threat of an injunction, to pay higher royalty rates, which would be passed on to consumers. There is nothing trivial or attenuated about these injuries; they are not outweighed by any offsetting consumer or competitive benefit; and they cannot be reasonably avoided by consumers. *See* Compl. ¶ 32. Commissioners Ramirez and Ohlhausen believe that these injuries are a significant departure from the type of injury contemplated by the Commission's 1980 Unfairness Policy Statement. Chairman Leibowitz and Commissioner Brill disagree. These injuries to end-use consumers as a result of Google's conduct are unique and particularly harmful, and use of the Commission's unfairness authority in this instance is appropriate and consistent with precedent. At this stage of the proceeding, Chairman Leibowitz and Commissioner Brill have a reason to believe that a violation has occurred based on these facts. If this matter were not being resolved through a Proposed Order, Chairman Leibowitz and Commissioner Brill would refrain from forming a final view on whether this evidence supports an unfair acts claim until after an administrative hearing, at which time the Commission would have the benefit of a full evidentiary record developed at trial.

Commissioner Ramirez dissents from the Commission's decision to use its unfair acts or practices authority to challenge Google's alleged violation of its FRAND commitments. In her view, the conduct and harm at issue fall squarely within Section 5's prohibition on unfair methods of competition but are a significant departure from the type of direct consumer transactions and immediate injury contemplated by the Commission's 1980 Unfairness Policy Statement. While there may be situations where it would be appropriate to allege an unfairness claim to address harm to competition or the competitive process, in this instance the claim neither reaches acts or injury not already encompassed by unfair methods of competition nor provides any additional relief. Under these circumstances, Commissioner Ramirez believes the majority's application of the Commission's unfairness authority is unwarranted.

[10] *See Robert Bosch,* Statement of the Federal Trade Commission, at 3 (''[Respondent]'s failure to abide by its commitment took place in the standard-setting context. In that setting, long an arena of concern to the Commission, a breach of contract risks substantial consumer injury. The standard setting context, together with the acknowledgment that a FRAND commitment also depends on the presence of a willing licensee, appropriately limit the Commission's enforcement policy and provide guidance to standard-setting participants.''), *available at http://www.ftc.gov/os/caselist/1210081/121126boschcommissionstatement.pdf; Negotiated Data Solutions,* Analysis of Proposed Consent Agreement to Facilitate Public Comment, at 6 (''A mere departure from a previous licensing commitment is unlikely to constitute an unfair method of competition under Section 5. The commitment here was in the context of standard-setting.''), *available at http://www.ftc.gov/os/caselist/0510094/080122analysis.pdf.*

[11] *Compare* Commissioner J. Thomas Rosch, The FTC's Section 5 Hearings: New Standards for Unilateral Conduct? (Mar. 25, 2009), at 6 (identifying the context of standard setting as a limiting principle for Section 5) *with* Complaint ¶¶ 1–4 (describing the effect of Google's alleged conduct on the standard setting process); Commissioner J. Thomas Rosch, Wading Into Pandora's Box: Thoughts On Unanswered Questions Concerning the Scope and Application of Section 2 & Some Further Observations on Section 5 (Oct. 3, 2009), at 20 (identifying monopoly power as a limiting principle for Section 5) *with* Complaint

We also disagree with Commissioner Ohlhausen's claim that the proposed settlement with Google creates uncertainty for market participants. In our view, it does just the opposite. By taking action that may deter the owners of standard-essential patents from unilaterally defining the terms of FRAND agreements through the exercise of leverage acquired solely through the standard-setting process, we protect the integrity of that process. Moreover, we believe the procedures outlined in the proposed settlement will provide useful guidance to market participants, including SSOs, in developing a predictable approach to resolve licensing disputes involving standard-essential patents. This will benefit all stakeholders, including patentees, implementers, and consumers.

We also believe that Commissioner Ohlhausen is incorrect in her claim that our allegations are in conflict with prior court rulings and in particular with certain findings of the district court in *Apple, Inc.* v. *Motorola Mobility, Inc.*[12] The court's determination in that case, made in connection with a decision on a motion *in limine*—not a trial on the merits—concerned the application of Wisconsin contract law. At most, the ruling suggests there is a question of fact as to whether Motorola's injunctive relief claims violated its contract with the SSOs.[13] The evidence before us provides us with sufficient reason to believe that a violation of Google and MMI's FRAND commitments occurred.[14]

Finally, we are not persuaded by Commissioner Ohlhausen's argument that the conduct alleged in the Commission's complaint implicates the First Amendment and the *Noerr-Pennington* doctrine. As noted above, we have reason to believe that MMI willingly gave up its right to seek injunctive relief when it made the FRAND commitments at issue in this case.[15] We do not believe that imposing Section 5 liability where a SEP holder violates its FRAND commitments offends the First Amendment because doing so in such circumstances ''simply requires those making promises to keep them.'' [16]

By direction of the Commission, Commissioner Rosch and Commissioner Ohlhausen abstaining.

Donald S. Clark,

Secretary.

[FR Doc. 2013–00837 Filed 1–15–13; 8:45 am]

BILLING CODE 6750–01–P

¶¶20–21 (alleging Google's monopoly power); Commissioner J. Thomas Rosch, The Path You Need Not Travel: Observations on Why Canada Can Do Without Section 5 (Feb. 4, 2010), at 5 (identifying harm to competition as a limiting principle for Section 5) *with* Complaint ¶ 28 (alleging harm to competition).

[12] 2012 U.S. Dist. LEXIS 181854, *35–46 (W.D. Wis. Oct. 29, 2012).

[13] The court denied Motorola's motion seeking a ruling that as a matter of law it could not have violated its FRAND commitments, establishing the existence of a fact issue. *Id.* at *45–46.

[14] We also disagree with our colleague as to the relevance of *Commonwealth Sci. & Indus. Research Organisation* v. *Buffalo Tech. Inc.,* 492 F. Supp. 2d 600 (E.D. Tex. 2007) (''CISRO''), to the Commission's action here. Commissioner Ohlhausen cites *CISRO* for the proposition that ''it should have been a reasonable expectation since that time [the decision of *CISRO* in 2007] to IEEE members (including affected parties here) that an injunction could issue in certain situations even on a RAND-encumbered SEP.'' *See* Dissenting Statement at 5. We agree that injunctions may issue in certain situations even when a RAND-encumbered SEP is involved, such as when a licensee is unwilling to license on FRAND terms—and have embedded this concept in the Proposed Decision and Order in both *Bosch* and this case.

[15] *See, e.g., Powertech Technology, Inc.* v. *Tessera, Inc.,* 2012 U.S. Dist. LEXIS 70630, *17–18 (N.D. Cal. May 21, 2012) (holding that when the patent holder had contracted away its rights to bring claims before the United States International Trade Commission, a challenge to a breach of that commitment was not barred by *Noerr*).

[16] *Cohen* v. *Cowles Media Co.,* 501 U.S. 663, 670–71 (1991).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–0915]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Ron Otten, at 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Formative Research to Support the Development of Sickle Cell Disease Educational Messages and Materials for the Division of Blood Disorders (0920–0915, Expiration 01/31/2013)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to improve the quality of life of people living with sickle cell disease (SCD). To accomplish this goal, CDC aims to address the need for educational messages and materials for adolescents, young adults, adults, and older adults living with SCD. CDC is interested in understanding the informational needs of these audiences related to the adoption of healthy behaviors and the prevention of complications associated with sickle cell disease. To develop valuable messages and materials, CDC will conduct formative focus groups with people with SCD across the country. Participants will stem from four urban centers as well as more remote, rural areas. Based on the findings from the formative focus groups, CDC will develop and test draft messages.

A total of 10 focus groups will be conducted. Eight focus groups with people with SCD would be held in four cities: Atlanta, GA; Detroit, MI; Oakland, CA; and Philadelphia, PA. Two in-person focus groups—one with males and one with females—will be conducted in each city with each target audience: adolescents aged 15–17, young adults aged 18–25, adults aged 26–35, and older adults 36 and over. To reach more rural participants, two telephone focus groups will be conducted: one with female adolescents aged 15–17 and a second with male older adults aged 36 and older.

The focus groups will be conducted with eight to nine participants in each and will last no more than 2 hours. The use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. In total, up to 90 people with SCD will participate in the focus group data collection. It is estimated that 120 potential participants will need to be screened to reach the target of 90 participants. The estimated

time per response for screening and recruitment is 12 minutes, for a total annualized burden of 204 hours.

This request is submitted to extend OMB clearance for one year. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Parents of adolescents (aged 15–17) living with SCD. Young adults (aged 18–25) living with SCD Adults (aged 26–35) living with SCD Older adults (aged 36+) living with SCD	Participant Screener and Recruitment Script.	120	1	12/60	24
Parents of adolescents (aged 15–17) living with SCD. Young adults (aged 18–25) living with SCD Adults (aged 26–35) living with SCD Older adults (aged 36+) living with SCD.	Focus Group Moderator's Guide	90	1	2	180
Total	.....	.....	.....	.....	204

Dated: January 8, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–00806 Filed 1–15–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–0745]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Colorectal Cancer Screening Program (OMB No. 0920–0745, exp. 6/30/2013)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Of cancers affecting both men and women, Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for adults starting at age 50 and continuing until age 75 years. Screening tests that are recommended by the United States Preventive Services Task Force, and that may be used alone or in combination, include fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, and colonoscopy.

In 2005, CDC established a three-year demonstration program, subsequently extended to four years, to screen low-income individuals 50 years of age and older who have no health insurance or inadequate health insurance for CRC. The five demonstration sites reported information to CDC including de-identified, patient-level demographic, screening, diagnostic, treatment, outcome and cost reimbursement data (Colorectal Cancer Screening Demonstration Program, OMB No. 0920–0745, exp. 7/31/2010). The information was used to assess the feasibility and cost effectiveness of a publicly funded screening program, describe key outcomes, and guide program expansion.

In 2009, CDC received additional funding from Congress and established the expanded Colorectal Cancer Control Program (CRCCP) to increase screening rates in the general population through evidence-based screening provision and screening promotion activities. All funded sites provide CRC screening and follow-up services to low-income men and women who are underinsured or uninsured for CRC screening. Funded sites also plan and implement program activities that promote CRC screening in the general population through policy, systems, community and individual level interventions. With expanded CRCCP support, the number of sites funded to provide CRC screening services increased from five to 26 and the original information collection was revised. Changes incorporated through the revision process included an increase in the number of respondents; simplification of the clinical data collection based on experience with the five demonstration program sites;

discontinuation of the cost reimbursement data collection; addition of an activity-based economic data collection; and deletion of the term ''Demonstration'' from the title. Information currently reported to CDC includes program-level activity cost data, and de-identified patient-level demographic, screening, diagnostic, treatment and outcome data (Colorectal Cancer Screening Program, OMB No. 0920–0745, exp. 6/30/2013).

CDC plans to request a three-year extension of the current approval. No changes are proposed to the content of the information collection, reporting procedures for awardees, or the estimated burden per respondent. However, the number of funded CRC screening sites will increase from 26 to 29.

Program awardees will continue to implement evidence-based interventions to increase population-level screening rates and to address disparities in access to CRC screening services.

Through this program, funded awardees will provide CRC screening services to low-income individuals 50 years of age and older who have no health insurance or inadequate health insurance for CRC. On average, each program awardee is expected to provide services to 375 individuals per year. De-identified clinical data elements will be reported to CDC electronically. In addition, each awardee will collect and report program-level activity-based cost data to CDC through an electronic Cost Assessment Tool (CAT). The activity-based cost information allows CDC to monitor individual awardees and compare activity-based costs across multiple sites and programs. A similar approach has been employed for a number of CDC-funded cancer programs (see Economic Analysis of the National Breast and Cervical Cancer Early Detection Program, OMB No. 0920–0776, exp. 3/31/2011, and Economic Analysis of the National Program of Cancer Registries, OMB No. 0920–0812, exp. 6/30/2012).

CDC will use the information collected from Colorectal Cancer Screening Program awardees to monitor and evaluate the CRC screening program and funded sites; improve the quality of screening and diagnostic services for underserved individuals; develop outreach strategies to increase screening; and report program results to Congress and other legislative authorities. Participation is required for all CRCCP awardees. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Colorectal Cancer Control Program Awardees.	Clinical Data Elements	29	375	15/60	2,719
	Cost Assessment Tool	29	1	22	638
Total					3,357

Dated: January 8, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–00755 Filed 1–15–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: School Readiness Goals and Head Start Program Functioning.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing a data collection as part of the ''School Readiness Goals and Head Start Program Functioning'' research project. The purpose of this study is to improve understanding of how local Head Start and Early Head Start programs define, measure, and communicate school readiness goals, and how they use these goals in program planning to improve program functioning. ACF is proposing to use a semi-structured telephone interview protocol to collect information from program directors and other key staff from approximately 60 local grantees and site visit protocols to collect further qualitative information through interviews and/or focus groups with program staff, oversight boards, key stakeholders, and parents in a subset of 12 of these grantees. ACF has contracted with the Urban Institute to collect and analyze the data gathered in the telephone interviews and site visits.

Topics to be covered in the telephone interview and site visit protocols include: A description of school readiness goals set by local grantee; the process used to set school readiness goals; contextual factors informing choices made about school readiness goals (e.g., needs of local children and families, program and staff characteristics, and community characteristics); how programs use and analyze data about school readiness goals; how programs report progress on goals; and how school readiness goals and data form program planning and improvement efforts.

Respondents: Head Start and Early Head Start program directors and managers closely involved with school readiness goal setting (e.g. education services coordinators); others in leadership positions (e.g. agency directors, center directors, home-based services coordinators or assistant program directors); front-line staff (e.g. Head Start teachers, Early Head Start teachers, home visitors, family service workers, and program specialists); members of Head Start governing bodies and local policy councils; liaisons from local education agencies; and parents with children in Head Start and Early Head Start programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Telephone Interview	120	1	0.75	90	90
Key Leaders Interview	24	1	1.5	36	36
Other Leaders Interview	30	1	1	30	30
Front-line Staff Interview	96	1	1	96	96
Governing Body/Policy Council Interview	72	1	1	72	72
Local Education Agency Interview	12	1	1	12	12
Parent Focus Group	144	1	1.5	216	216

Estimated Total Annual Burden Hours: 552.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2013–00593 Filed 1–15–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Mother and Infant Home Visiting Program Evaluation: Follow-up data collection on family outcomes.

OMB No.: 0970–0402.

Description: In 2011, the Administration for Children and Families (ACF) and Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS) launched a national evaluation called the Mother and Infant Home Visiting Program Evaluation (MIHOPE). This evaluation, mandated by the Affordable Care Act, will inform the federal government about the effectiveness of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program in its first few years of operation, and provide information to help states develop and strengthen home visiting programs in the future. MIHOPE has two phases. Phase 1 includes baseline data collection and implementation data; Phase 2 includes follow up data collection. OMB approved a data collection package for Phase 1 in July 2012. The purpose of the current document is to request approval of data collection efforts for Phase 2.

Data collected during Phase 2 will include the following: (1) A one-hour family follow-up survey, (2) 30-minutes of observed interactions between the parent and child, (3) a direct assessment of child development, (4) measurement of mother's weight and child's height and weight, (5) collection of saliva from the mother and child for purposes measuring cotinine, an indicator of smoking behavior and exposure to second-hand smoke, and cortisol, an indicator stress exposure and regulation, and (6) extend collection of weekly home visitor logs on home visiting services until a family is no longer receiving services.

Data collected during Phase 2 will be used to estimate the effects of MIECHV-funded programs on seven domains specified for the evaluation in the ACA: (1) Prenatal, maternal, and newborn health; (2) child health and development, including maltreatment, injuries, and development; (3) parenting; (4) school readiness and academic achievement; (5) crime or domestic violence; (6) family economic self-sufficiency; and (7) use of other community resources. Data collected during Phase 2 will also be used to assess the differences in services used between families who receive home visiting and a comparison group, and to assess the quantity of home visiting services received by families.

Respondents: The respondents in Phase 2 will include 4335 parents who are enrolled in the study. Data collection activities will take place over a three-year period.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Home visitor logs	170	50	0.09	765
Family follow-up survey	1445	1	1.0	1445
Direct parent-child interactions	2890	1	0.5	1445
Direct child assessments	1445	1	0.7	1012

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Collecting saliva to measure cotinine and cortisol, and measuring height and weight	2890	1	0.3	867

Estimated Total Annual Burden Hours: 5,334

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration, for Children and Families.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2013–00592 Filed 1–15–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by February 15, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0645. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803 (OMB Control Number 0910–0645)—Revision

The FDA Safety Reporting Portal (the SRP) (formerly referred to as the MedWatch^{Plus} Portal and Rational Questionnaire) and the Electronic Submission Gateway (ESG) are the Agency's electronic systems for collecting, submitting, and processing adverse event reports and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). Many of the adverse event reports submitted to FDA are currently filed in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, approved under OMB control numbers 0910–0284 and 0910–0291. This notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, approved under OMB control number 0910–0645.

I. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive three types of adverse event reports electronically via the SRP using rational questionnaires. FDA sought comments on the extension of OMB approval for the existing three rational questionnaires, as well as comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the Center for Tobacco Products (CTP).

A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines ''reportable food'' as an ''article of food (other than infant formula or dietary supplements) for which there is a reasonable

probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. To further the development of the RFR, section 417 of the FD&C Act required FDA to establish an electronic portal by which instances of reportable food (''RFR reports'') must be submitted to FDA by responsible parties and may be submitted by public health officials. A ''responsible party'' is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. The RFR electronic portal was established in 2009 as part of the MedWatch^{Plus} Portal, now the SRP, and approved under OMB control number 0910–0645.

The Congressionally identified purpose of the RFR is to provide ''a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health'' (121 Stat. 965). The RFR reports are designed to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (Pub. L. 111–353) (the legislation or FSMA). Section 211 of the legislation amended section 417 of the FD&C Act to require FDA to collect additional information in the Agency's RFR reports: (1) A description of the article of food; (2) affected product identification codes, such as universal product code (UPC), stock keeping unit, or lot or batch numbers sufficient for the consumer to identify the article of food; (3) contact information for the responsible party; and (4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

Section 211 of FSMA also amended section 417 of the FD&C Act to require FDA to generate one-page notices from RFR reports to post on *www.fda.gov* for grocery stores to display to consumers when a reportable food has been sold. The amendment made by section 211 of FSMA took effect June 4, 2012, 18 months after the date of enactment. To comply with this statutory deadline, FDA initially obtained OMB approval of the additional collection of information requirements under the emergency processing provisions of the PRA under OMB control number 0910–0709. The new data improves the RFR's effectiveness in carrying out its purpose of tracking patterns of adulteration in food and supporting FDA's efforts to target limited inspection resources to protect the public health.

Table 1 of this document, entitled ''New Data Elements for RFR Reports,'' presents the new data elements added by FDA to RFR Reports on June 4, 2012.

TABLE 1—NEW DATA ELEMENTS FOR RFR REPORTS

Field text	Mandatory or optional input	Authority if mandatory
Reason this food is reportable (agent)	Mandatory	Section 417(e)(4) of the FD&C Act.
What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?	Mandatory	Section 417(e)(5) of the FD&C Act.
How did you determine which products/lots/batches were affected?	Mandatory	Section 417(e)(4) and (5) of the FD&C Act.
To the best of your knowledge, has all of the reportable food been removed from commerce?	Mandatory	Section 417(e)(6) of the FD&C Act.
What corrective actions have been taken to prevent future occurrences?	Optional.	
Product commodity type	Mandatory	Section 417(e)(3) of the FD&C Act.
Manufacturing/production date(s)	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Use-by dates, if any, or approximate shelf life	Mandatory	Section 417(e)(7) of the FD&C Act.
Was product treated to reduce microorganisms?	Mandatory (but conditional)	Section 417(e)(3) and (4) of the FD&C Act.
Microbial reduction treatment details	Mandatory (but conditional)	Section 417(e)(3) and (4) of the FD&C Act (Conditional for microbial hazards only and only after ''yes'' answer to ''Was product treated to reduce microorganisms?'').
Is a bacterial isolate available for collection?	Mandatory (but conditional)	Section 417(e)(4) of the FD&C Act (Conditional for microbial hazards only.)
Animal species intended for	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Life stage of animal intended for	Mandatory	Section 417(e)(3) and (4) of the FD&C Act.
Have you notified all immediate previous sources of this reportable food?	Optional.	
Have you notified all immediate subsequent recipients of this reportable food?	Mandatory	Section 417(e)(6) of the FD&C Act.

In this request for extension of OMB approval, FDA is combining the burden hours associated with OMB control number 0910–0709 with the burden hours approved under this OMB control number (0910–0645).

B. Reports Concerning Experience With Approved New Animal Drugs

Section 512(*l*) of the FD&C Act (21 U.S.C. 360b(*l*)) and § 514.80(b)) require applicants of approved new animal drug

applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

If an applicant must report adverse drug experiences and product/manufacturing defects and chooses to do so using the Agency's paper forms, the applicant is required to use Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs'' (see § 514.80(d)). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects. Collection of information using existing paper forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910–0284. Alternatively, an applicant may choose to report adverse drug experiences and product/manufacturing defects electronically. Collection of this information electronically was approved in 2010 under OMB control number 0910–0645. The electronic submission data elements to report adverse drug experiences and product/manufacturing defects electronically remain unchanged in this request for extension of OMB approval.

C. Pet Food Early Warning System

Section 1002(b) of FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food.

FDA developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, to make it easy for the public to report a safety problem with pet food. The Pet Food Early Warning System is designed to identify adulteration of the pet food supply and outbreaks of illness associated with pet food to enable FDA to quickly identify, track and remove from commerce such articles of food. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. In 2010, OMB approved the Pet Food Early Warning System component of the SRP under OMB control number 0910–0645, and FDA launched the rational questionnaire by which consumers may electronically report adverse events associated with pet food. The electronic submission data elements to report adverse events associated with pet food remain unchanged in this request for extension of OMB approval.

D. Voluntary Tobacco Product Adverse Event and Product Problem Reports

As noted, this notice seeks comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the CTP to collect voluntary tobacco product adverse event and product problem reports.

FDA has broad legal authority under the FD&C Act to protect the public health. CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The Family Smoking Prevention and Tobacco Control Act of 2009 (Pub. L. 111–31) (Tobacco Control Act) amended the FD&C Act by creating a new section 909 (21 U.S.C. 387i, Records and Reports on Tobacco Products). Section 909(a) of the FD&C Act (21 U.S.C. 387i(a)) authorizes FDA to establish regulations with respect to mandatory adverse event reports associated with the use of a tobacco product. At this time, FDA is proposing to collect voluntary adverse event reports associated with the use of tobacco products from interested parties such as health care providers, researchers, consumers and other users of tobacco products. Information collected in voluntary adverse event reports will contribute to CTP's ability to be informed of, and assess the real consequences of, tobacco product use. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

CTP currently receives adverse event and product problem reports primarily via paper MedWatch forms, approved under OMB control number 0910–0291. MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products, do not specifically include questions relevant for the analysis of adverse events or product problems related to tobacco products. The proposed voluntary tobacco product adverse event and product problem rational questionnaire will include these specific questions. The questionnaire evolved with input from a National Institutes of Health team of human-factors experts, from other regulatory Agencies, and with extensive input from consumer advocacy groups and the general public. FDA is also working with the FDA Internet team to follow the Department of Health and Human Services Internet guidelines for Web design. FDA has and will continue to reach out to professional organizations and community interest groups to collect feedback during the user acceptance testing. The rational questionnaire will provide the user with detailed navigation instructions to include drop-down menus, lists of values, controlled vocabularies, and mouse over help where possible. In addition, CTP will issue guidance for the rational questionnaire. Finally, we note that users who are unable to submit reports using the electronic system will still be able to provide their information by paper form (by mail or FAX) or telephone.

The proposed voluntary tobacco product adverse event and product problem rational questionnaire requests the following information:

Introductory Information About the Submission

- Whether the submission is a new report, or a followup or amendment to a previously transmitted report.

Information About the Sender and the Affected Person

- Unless the sender wishes to remain anonymous, the name of and contact information for the person sending the report; and
- Unless the affected person wishes to remain anonymous, the name, contact

information, and demographic information for the person who experienced the adverse event.

Details of Any Attachments

- The type of attachment and a description of it.

Tobacco Product Details

- Information about the product that is the subject of the report, such as the brand name, product name, UPC, and a description of the tobacco product or component;
- Information about the product or component purchase date and location; and
- Information about the manufacturer of the product or component.

Problem Summary

- Information about the product problem or adverse event, such as the date and duration of the problem or adverse event, a description of the use of the product, a description of the product problem or adverse event, and a description of the main symptoms or health problems.
- Information about the medical treatment received by the affected person, such as whether the person was taken to an emergency facility, a description of any medical testing or treatment performed, and the results of any tests;
- Information about any similar product problems or adverse events previously had by the affected person; and
- In the event of death, the date of death and the reported cause of death.

Other Products Used

- Information about the affected person's use of other tobacco products, alcohol, prescription medications, over-the-counter medications, vitamins, or dietary supplements.

The rational questionnaire will capture tobacco-specific adverse event and product problem information from voluntary reporting entities such as health care providers, researchers, consumers, and other users of tobacco products. To carry out its responsibilities, FDA needs to be informed when an adverse event, product problem, or error with use is suspected or identified. When FDA receives tobacco-specific adverse event and product problem information, it will use the information to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

In the **Federal Register** of September 14, 2012 (77 FR 56847), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

II. Information Collection Burden Estimate

Description of respondents: The respondents to this collection of information include all persons submitting mandatory or voluntary adverse event reports electronically to FDA via the ESG or the SRP.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Adverse Event Report via the SRP (Other than RFR Reports).	3800	1,513	1	1,513	0.6 (36 minutes)	908
Mandatory Adverse Event Report via the SRP (Other than RFR Reports).	3800	636	1	636	1	636
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission).	3800	1,491,228	1	1,491,228	0.6 (36 minutes)	894,737
Mandatory and Voluntary RFR Reports via the SRP.	3800	1,413	1	1,413	0.6 (36 minutes)	848
Total						897,129

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Agency's estimate of the number of respondents and the total annual responses in table 2, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Followup reports, if any, are not counted as new reports. Based on its experience with adverse event reporting, FDA estimates that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

Voluntary adverse event reports submitted via the SRP (other than RFR Reports) include reports associated with pet food (the Pet Food Early Warning System) and the new tobacco product adverse event and product problem reports. The Center for Veterinary Medicine (CVM) received 845 pet food adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012, and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CVM estimates that it will receive, on average, 1,413 pet food reports annually over the next 3 years. CTP estimates that it will receive approximately 100 voluntary tobacco product adverse event and product problem reports annually, after implementation of electronic reporting. CTP received 27 reports in 2010, 30 reports in 2011, and 22 reports in the first half of 2012, and estimates that for the full 12 months of 2012 it will receive over 40 reports. Based on this experience and an expectation that reporting will increase once electronic

reporting is launched, CTP estimates that it will receive, on average, 100 voluntary adverse event and product problem reports annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 1,513 voluntary adverse event reports submitted via the SRP, with a burden of 907.8 hours, rounded to 908 hours, as reported in table 2, row 1 (1,413 + 100 = 1,513).

Mandatory adverse event reports submitted via the SRP (other than RFR Reports) include reports of adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. CVM received 144 such adverse event reports in 2010, 537 reports in 2011, and 212 reports in the first four months of 2012, and estimates that for the full 12 months of 2012 it will receive 636 reports. Based on this experience, CVM estimates that it will receive, on average, 636 reports of adverse drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 636 mandatory adverse event reports submitted via the SRP, with a burden of 636 hours, as reported in table 2, row 2.

Adverse event reports submitted via the ESG include reports of adverse experiences related to drugs, biological products, and medical devices, as well as, adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. FDA received 586,229 such adverse event reports in 2010; 850,161 reports in 2011; and 497,076 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,491,228 reports. Based on this experience, FDA estimates that it will receive, on average, 1,491,228 adverse event reports submitted via the ESG, with a burden of 894,736.8 hours, rounded to 894,737 hours, as reported in table 2, row 3.

FDA estimates that over the next 3 years it will receive annually 1,413 mandatory and voluntary RFR Reports submitted via the SRP, as reported in table 2, row 4. The Center for Food Safety and Applied Nutrition (CFSAN) received 845 such adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first four months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CFSAN estimates that it will receive, on average, 1,413 mandatory and voluntary RFR Reports submitted via the SRP annually over the next 3 years, with a burden of 847.8 hours, rounded to 848 hours, as reported in table 2, row 4.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291.

While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: January 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00761 Filed 1–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Optical Microscope Software for Breast Cancer Diagnosis

Description of Technology: The instant invention discloses a software to analyze optical microscopic images of human breast tissue sections for diagnosing cancer by using the differences in spatial positioning of certain genes. The software uses the inherent hierarchy in the data and stores all the analysis and manual interaction information in a highly structured XML file. It is a user-friendly software to discriminate normal and cancerous human breast tissue section images that can be used for large experiments. Additionally the software uses a cluster of computers in the background to reduce the analysis time for large image datasets. Furthermore, the software of instant invention provides a set of tools for performing diagnostic or prognostic assays on new unseen datasets.

Potential Commercial Applications:

- The software could be an essential part of an integrated diagnostic or prognostic assay for breast cancer detection.
- The software could be a key tool for biomedical research to test new markers and their applicability for diagnostic purposes.
- The use of the software could provide important information for understanding the underlying causes of gene repositioning.

Competitive Advantages:

- The software of instant invention can be used to analyze relatively large datasets.
- To reduce the processing time by at least 10 fold.
- The software can be used in a broad range of quantitative image analysis applications.

Development Stage:

- Prototype
- Clinical
- In vitro data available (human)

Inventors: Kaustav Nandy (SAIC-Frederick, Inc), Stephen J. Lockett (SAIC-Frederick, Inc), Prabhakar R. Gudla (SAIC-Frederick, Inc), William Cukierski (NCI), Renee Qian (NCI), Karen J. Meaburn (NCI), Tom Misteli (NCI).

Publications:

1. Gudla PR, *et al.* A high-throughput system for segmenting nuclei using multiscale techniques. Cytometry A. 2008 May;73(5):451–66. [PMID 18338778]

2. Nandy K, *et al.* Automatic nuclei segmentation and spatial FISH analysis for cancer detection. Conf Proc IEEE Eng Med Biol Soc. 2009;2009:6718–21. [PMID 19963931].

3. Meaburn KJ, *et al.* Disease-specific gene repositioning in breast cancer. J Cell Biol. 2009 Dec 14;187(6):801–12. [PMID 19995938].

4. Cukierski WJ, *et al.* Ranked retrieval of segmented nuclei for objective assessment of cancer gene repositioning. BMC Bioinformatics. 2012 Sep 12;13:232. [PMID: 22971117].

5. Nandy K, *et al.* Supervised learning framework for screening nuclei in tissue

sections. Conf Proc IEEE Eng Med Biol Soc. 2011;2011:5989–92. [PMID 22255704]

Intellectual Property: HHS Reference No. E–286–2012/0—Software. Patent protection is not being pursued for this technology.

Licensing Contact: Susan Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The SAIC-Frederick Optical Microscopy and Analysis Laboratory is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact John Hewes, Ph.D., at *hewesj@mail.nih.gov*.

Simple Direct Zirconium-89 Cell PET Label, ^{89}Zr-Labeled Cells, and Methods for Real-Time In Vivo Pet Imaging

Description of Technology: The capability to image cells and cellular processes in real time over a scale of days could dramatically improve research insights and the effectiveness of cell-based therapies. Zirconium-89 (^{89}Zr) has a half-life of over three days (78.4 hours) over 44 times longer compared to Fluorine (^{18}F) the most commonly used PET isotope (half-life of 1 hour and 50 minutes). ^{89}Zr is also advantageous compared to other long half-life isotopes because it is not limited by high background activity and cell toxicity. Labeling cells with ^{89}Zr, is currently accomplished by indirect methods using secondary cell-type specific reagents such as antibodies. This technology is a PET imaging complex of ^{89}Zr and polycation that is internalized by the cells. This complex has been able to directly label a wide range of cells, without the use of secondary reagents. ^{89}Zr-labeled cells of lymphocytic lineage, including T cells, natural killer T-cells, macrophages, dendritic cells, and stem cells, have been produced and imaged in vivo with minimal damage to the cells. This PET imaging agent can be readily combined with an MR imaging agent for combined PET/MR imaging of cells. The imaging capabilities enabled by this technology may significantly improve cell therapies, cell level diagnostics and aid research for non-cell based therapies.

Potential Commercial Applications:

- Imaging
- Diagnostic
- Cell therapies
- Transplantation and transfusion

Competitive Advantages:

- Direct labeled cells (versus indirect techniques)
- Longer half-life
- Not limited by high background activity and cell toxicity

Development Stage:

- Early-stage
- Pre-clinical
- In vivo data available (animal)

Inventors: Omer Aras (CC), Peter Choyke (NCI), Joseph Frank (CC), Noriko Sato (CC), Jeremy Pantin (NHLBI).

Intellectual Property: HHS Reference No. E–056–2012/0—US Provisional Application No. 61/611964 filed 16 Mar 2012.

Licensing Contact: Tedd Fenn; 301–435–5031; *Tedd.Fenn@nih.gov*

Collaborative Research Opportunity: The NCI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact John Hewes, Ph.D., at *hewesj@mail.nih.gov.*

Small, Stable, Functional, Soluble, Monomeric IgG1 Fc Molecules Engineered Therapies

Description of Technology: This technology relates to small (~27 kDa) antibody fragments that are potentially useful for therapeutic development. These are monomeric IgG fragment crystalizable (mFc) compositions; they are long half-lived, functional (pH dependent binders of neonatal Fc receptor—FcRn); and they are soluble and express efficiently in E. coli. These molecules may serve as a platform for development of engineered mFc-based antibodies and fusion proteins with therapeutic applications. Efforts to engineer antibody-based therapeutics, to date, have encountered technical limitations due to the relatively large fragment size and short fragment half-life. The IgG fragment crystalizable (Fc) is a dimer of two constant domains (CH2–CH3 chains). Fc has a long half-life, which makes it promising as a candidate for engineering antibody therapeutics. Fusion proteins based on Fc dimer molecules demonstrate extended half-life, due to the ability to bind FcRn at acidic pH. However, the relatively large size of the Fc domains (~50 kD) is not optimal. This technology uses smaller (~27 kDa) mFc compositions that retain efficient binding to human FcRn and demonstrate long half-life. These mFc compositions are promising for the development of novel therapeutics because the smaller size may allow for superior access to targets and tissues compared to full sized mAbs and larger fragment-based therapeutics, while also retaining important function characteristics.

Potential Commercial Applications: Therapeutics—human and veterinary, engineered antibody and fusion proteins.

Competitive Advantages: Smaller size results better tissue penetration, reduced steric hindrance, increased therapeutic efficiency and lower cost.

Development Stage:

- Early-stage
- Pre-clinical

Inventors: Dimiter S. Dimitrov and Tianlei Ying (NCI).

Publication: Ying T, *et al.* Soluble monomeric IgG1 Fc. J Biol Chem. 2012 Jun 1; 287(23):19399–408. [PMID 22518843].

Intellectual Property: HHS Reference No. E–019–2012/0—U.S. Patent Application No. 61/612,138 filed 16 Mar 2012.

Related Technologies: HHS Reference No. E–003–2007/0—

- U.S. Patent Application No. 61/063,245 filed 31 Jan 2008
- PCT Application No. PCT/US2009/0326 and related international applications filed on 30 Jan 2009 in Australia, Canada, China, Europe, Japan, and India
- U.S. Patent Application No. 12/864,758 filed 27 Jul 2010

Licensing Contact: Tedd Fenn; 301–435–5031; *Tedd.Fenn@nih.gov*

Collaborative Research Opportunity: The NCI/CCR/NP is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Small, Stable, Functional, Soluble, Monomeric IgG1 Fc Molecules Engineered Therapies. For collaboration opportunities, please contact John Hewes, Ph.D., at *#hewesj@mail.nih.gov.*

Virus-Like Particles Mediated Protein and RNA Delivery

Description of Technology: The invention is directed to novel virus-like particles (VLPs) that are capable of binding to and replicating within a target mammalian cell, including human cells. The claimed VLPs are safer than viral delivery because they are incapable of re-infecting target cells. The present VLPs can optionally comprise inhibitory recombinant polynucleotides, such as microRNA, antisense RNA or small hairpin RNA, to down regulate or turn off expression of a particular gene within the target cell. Alternatively, recombinant polynucleotides packaged within VLPs can comprise a gene encoding a therapeutic protein so as to enable expression of that protein within the

target cell. Specifically, VLPs of the invention are composed of an alphavirus replicon that contains a recombinant polynucleotide, a retroviral gag protein, and a fusogenic envelope glycoprotein.

While the claimed VLPs have a variety of applications, therapeutic uses of the VLPs include directing antibody synthesis and converting cancer cells into antigen presenting cells. Additional applications include using VLPs to induce fast (approx. 3–4 hrs) and high levels of protein production in mammalian cells.

Potential Commercial Applications:

- Delivery of microRNA and small hairpin RNA to reduce express of targeted genes in a human cell
- Delivery of coding RNA for robust expression in mammalian systems
- Direct antibody production by in vivo injection of replicons (no antigen purification)
- Therapeutic applications

Competitive Advantages:

- High level (~million copies per cell) of RNA production/synthesis within target cell
- Fast expression (approx. 3–4 hrs compared to 1–2 days) following VLP introduction into target cells
- Obviates need to use expensive antigen purification for proteins or antigens produced inside target cells

Development Stage:

- Pilot
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Stanislaw J. Kaczmarczyk and Deb K. Chatterjee (NCI).

Intellectual Property: HHS Reference No. E–264–2011/0—US Application No. 61/615,687 filed 26 Mar 2012.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *lauren.nguyen-antczak@nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Novel Delivery of Packaged RNA to Mammalian Cells. For collaboration opportunities, please contact Kevin Brand at *brandk@mail.nih.gov.*

A Combinatorial Cloning Platform for Construction of Expression Vectors for Protein Production

Description of Technology: The Combinatorial Cloning Platform (CCP) of this invention is a collection of vectors for use with the Gateway Multisite Recombination System (Life Technologies). The CCP that is currently available includes plates of 192 glycerol stocks of *E. coli* each containing one of the library plasmids, and a collection of 24 DNAs that are the downstream vectors for expression in different hosts. Uses of this CCP include construction of protein expression constructs with various fusion tags, generation of expression constructs with different promoters for *in vivo* expression, and production of clones with fluorescent tags for localization experiments. The advantage of the CCP is based on the exquisite specificity of the Multisite Gateway reactions, which permit linkage of multiple elements in a directional fashion and involve no additional DNA amplification. There is also no need for restriction-based cloning processes, which have a high rate of failure and may require optimization depending on the sites available in a given clone. The CCP library includes clones for fluorescent and luminescent reporters, epitope and solubility fusion tags, bimolecular fluorescence complementation (BiFC) fusions, 18 different eukaryotic promoters, and many other useful clones. In addition, the destination vector collection contains two flavors of Gateway destination vectors for *E. coli,* baculovirus, mammalian, and lentiviral expression.

Potential Commercial Applications:

- Construction of protein expression constructs with various fusion tags
- Generation of expression constructs with different promoters for in vivo expression
- Production of clones with fluorescent tags for localization experiments
- Generation of constructs for making mutant cell lines or transgenic animals
- Production of vectors for shRNA or miRNA delivery

Competitive Advantages: The CCP is considerably more flexible than currently available commercial systems for construction of protein expression constructs.

Development Stage:

- Prototype
- Pre-clinical
- In vitro data available

Inventor: Dominic Esposito (NCI).

Publication: Hopkins RF, *et al.* Optimizing transient recombinant protein expression in mammalian cells. Methods Mol Biol. 2012;801:251–68. [PMID 21987258].

Intellectual Property: HHS Reference No. E–164–2011/0—Research Tools. Patent protection is not being pursued for these technologies.

Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Therapeutic Peptide Treatment for Dyslipidemic and Vascular Disorders

Description of Technology: This invention is directed to use of certain peptide analogs comprising multiple amphipathic helical domains that are able to promote cellular lipid efflux and stimulate lipoprotein lipase activity. As a result, administration of invention peptides lead to reduced incidences of hypertriglyceridemia without inducing toxicity. Existing peptides that stimulate efflux of lipids from cells exhibit unacceptably high toxicity. Invention peptides are superior to existing peptides and can also be used to treat or prevent a vast range of vascular diseases, and their dyslipidemic precursors. Exemplary vascular diseases and conditions that could benefit from treatment with the invention peptides include: dyslipidemia, hyperlipidemia, hypercholesterolemia, HDL deficiency, coronary heart disease, atherosclerosis, and thrombic stroke.

Potential Commercial Applications:

- Treatment of dyslipidemic and vascular disorders
- Method of identifying therapeutic non-cytotoxic peptides

Competitive Advantages:

- Specific control of lipid efflux and transport
- Transient hypertriglyceridemia with no reported toxicity

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Alan T Remaley and Marcelo A Amar (NHLBI).

Publications:

1. Remaley AT, *et al.* Synthetic amphipathic helical peptides promote lipid efflux from cells by an ABCA1-dependent and an ABCA1-independent pathway. J Lipid Res. 2003 Apr;44(4):828–36. [PMID 12562845].
2. Sviridov DO, *et al.* Helix stabilization of amphipathic peptides by hydrocarbon stapling increases cholesterol efflux by the ABCA1 transporter. Biochem Biophys Res Commun. 2011 Jul 8;410(3):446–51. [PMID 21672528].
3. Osei-Hwedieh DO, *et al.* Apolipoprotein mimetic peptides: Mechanisms of action as anti-atherogenic agents. Pharmacol Ther. 2011 Apr;130(1):83–91. [PMID 21172387].

Intellectual Property: HHS Reference No. E–138–2008/0—US Patent Application No. 12/937,974 filed 14 Oct 2010.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; l*auren.nguyen-antczak@nih.gov.*

Dated: January 10, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–00738 Filed 1–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

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Transmission-Blocking Malaria Vaccine

Description of Technology: There is no vaccine for malaria, and there is growing resistance to existing anti-malarial drugs. Sexual stage-specific antigens are of interest as vaccine candidates because disruption of these antigens would reduce the fertility and, thus, the infectivity of the parasite.

This invention claims methods and compositions for delivering a *Plasmodium* P47 vaccine or antibody to P47 to prevent *Plasmodium falciparum* or *Plasmodium vivax* malaria. P47 and other antigens have been mentioned as potential transmission-blocking vaccines due to their surface location on gametes. The gene for P47 antigens is also well characterized. Recent discoveries have noted that P47 allows the parasite to suppress or evade the immune system, thereby ensuring the mosquitoes' survival. Recent discoveries have also shown the mechanism by which P47 enables survival of the parasite by manipulation of the mosquito immune system. Based on the critical role of P47 antigens in transmission, the disruption of the function of P47 by various means can be an innovative and forceful means to control and/or reduce the prevalence of malaria.

Potential Commercial Applications: Malaria vaccine, diagnostic and therapeutic.

Competitive Advantages:

- Single protein malaria transmission-blocking vaccine.
- Cost-effective, simple manufacturing process for vaccine.
- Potentially lower-cost malarial vaccine for developing/developed countries.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Carolina Barillas-Mury and Alvaro Molina-Cruz (NIAID).

Publication: Molina-Cruz A, et al. Some strains of Plasmodium falciparum, a human malaria parasite, evade the complement-like system of Anopheles gambiae mosquitoes. Proc Natl Acad Sci U S A. 2012 Jul 10;109(28):E1957–62. [PMID 22623529]

Intellectual Property: HHS Reference No. E–222–2012/0 — US Application No. 61/684,333 filed 17 Aug 2012.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases (NIAID) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize malaria vaccines, diagnostics and therapeutics. For collaboration opportunities, please contact Tristan J. Mahyera at *tristan.mahyera@nih.gov* or 301–827–0251.

Methods and Composition for Identification of Variants of JC Virus DNA; An Etiologic Agent for Progressive Multifocal Leukoencephalopathy (PML)

Description of Technology: JC Virus causes a fatal disease in the brain called progressive multifocal leukoencephalopathy (PML) that occurs in many patients with immunocompromised conditions. The finding of JCV DNA in the patients with neurological symptoms of PML is a diagnostic criterion and is needed to confirm the diagnosis of PML to rule out other neurological conditions. Certain JC virus variants are known to have a greater association with PML. For example, ''Prototype'' JC virus is far more pathogenic than ''Archetype'' JC virus.

This invention claims novel assays for identifying Archetype and/or Prototype JC virus by detecting the presence or absence of the unique Archetype nucleic acid sequence in the non-coding regulatory region of JC virus. While the sequences of Archetype and Prototype JC virus are known, these are the first assays that allow discrimination between Prototype and Archetype JC virus in a simple assay without the need for DNA sequencing. The identification of a JC virus as a prototype can lead to early treatment of infected individuals.

Potential Commercial Applications:

- JCV diagnostic kits.
- JCV diagnostics.

Competitive Advantages:

- DNA sequencing not required.
- Single assay format using same template to identify prototype and archetype with 10c/ml sensitivity.

Development Stage:

- Clinical.
- In vitro data available.
- In vivo data available (human).

Inventors: Eugene O. Major and Caroline F. Ryschkewitsch (NINDS).

Publication: Perkins MR, et al. Changes in JC Virus-Specific T Cell Responses during Natalizumab Treatment and in Natalizumab-Associated Progressive Multifocal Leukoencephalopathy. PLoS Pathog. 2012 Nov;8(11):e1003014. [PMID 23144619]

Intellectual Property: HHS Reference No. E–088–2012—US Application No. 61/661,289 filed 18 Jun 2012.

Related Technology: HHS Reference No. E–152–2009/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize assays for the detection of JC Virus. For collaboration opportunities, please contact Melissa Maderia at *maderiam@mail.nih.gov* or 301–451–3943.

Cross-Reactive Dengue Fully Human Monoclonal Antibodies

Description of Technology: Among the arthropod-borne flaviviruses, the four dengue virus serotypes, dengue type 1 virus (DENV–1), dengue type 2 virus (DENV–2), dengue type 3 virus (DENV–

3), and dengue type 4 virus (DENV–4) are most important in terms of human morbidity and geographic distribution. Dengue viruses cause dengue outbreaks and major epidemics in most tropical and subtropical areas where *Aedes albopictus* and *Aedes aegypti* mosquitoes are abundant.

A safe and effective vaccine against dengue is currently not available. Passive immunization with monoclonal antibodies from non-human primates or humans represents a possible alternative to vaccines for prevention of illness caused by dengue virus. This invention claims fully human monoclonal antibodies that bind and neutralize dengue type 1, 2, 3 and 4 viruses. It also claims fragments of such antibodies and nucleic acids encoding the antibodies of the invention as well as prophylactic, therapeutic and diagnostic methods employing the antibodies and nucleic acids of the invention.

Potential Commercial Applications:

- Prophylaxis/therapy against dengue serotypes 1, 2, 3, and 4.
- Dengue diagnostics.

Competitive Advantages:

- Antibodies are cross-reactive with all four serotypes of dengue.
- Antibodies are fully human.

Development Stage:

- Pre-clinical.
- In vitro data.

Inventors: Dimiter S. Dimitrov and Zhongyu Zhu (NCI).

Intellectual Property: HHS Reference No. E–273–2011/0—US Application No. 61/646,638 filed 14 May 2012.

Related Technologies: HHS Reference No. E–066–2003/5—US Patent 7,622,133 issued 24 Nov 2009; US Application No. 12/607,035 filed 27 Oct 2009.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The NCI/CCR/NP is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Cross-Reactive Dengue Fully Human Monoclonal A. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Typhoid-Plague Bivalent Vaccine

Description of Technology: Yersinia pestis (*Y. pestis*) bacteria is the causative agent of plague, typically transmitted from animals to humans by the bite of an infected flea. *Y. pestis* infection of the lungs leads to pneumonic plague, which is highly contagious and generally fatal. *Y. pestis* is a potential bioterrorist threat agent for which no vaccine yet exists.

This invention claims the generation and development of a candidate oral vaccine against plague. The vaccine consists of a synthetic gene construct that expresses a *Y. pestis* F1–V fusion antigen linked to a secretion signal, resulting in the production of large amounts of the F1–V antigen. The F1–V synthetic gene fusion is housed within Ty21a, an attenuated typhoid fever strain that is licensed for human use as a live oral bacterial vaccine. Ty21a serves as a carrier to deliver the F1–V fusion antigens of the plague bacteria; the combined F1–V fusion in the Ty21a carrier has been shown to stimulate a robust immune response in mice. The possibility of combining the oral plague vaccine of this invention with FDA's candidate oral anthrax vaccine exists and would result in an easy-to-administer oral delivery system to streamline administration of the vaccine to large numbers of recipients in emergency situations.

Potential Commercial Applications: Plague vaccines, therapeutics and diagnostics.

Competitive Advantages:

- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Dennis J. Kopecko, Manuel A. Osorio, Monica R. Foote (FDA/CBER).

Intellectual Property: HHS Reference No. E–105–2011/0—US Application No. 61/650,676 filed 23 May 2012.

Related Technologies: HHS Reference No. E–344–2003/1—US Patent 7,758,855 issued 20 Jul 2010; US Patent 8,247,225 issued 21 Aug 2012.

Licensing Contact: Peter A. Soukas; 301–435–4616; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research, Lab of Enteric and Sexually Transmitted Diseases, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize oral plague vaccine. For collaboration opportunities, please contact Dennis Kopecko at *dennis.kopecko@fda.hhs.gov.*

Dated: January 10, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–00737 Filed 1–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0076]

Privacy Act of 1974; Department of Homeland/U.S. Customs and Border Protection—002 Global Enrollment System (GES), System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Homeland Security proposes to update and reissue the Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Customs and Border Protection—002 Global Enrollment System'' system of records. This system of records allows the Department of Homeland Security/U.S. Customs and Border Protection to collect and maintain records on individuals who voluntarily provide personally identifiable information to U.S. Customs and Border Protection in return for enrollment in a program that will make them eligible for expedited processing at designated U.S. border ports of entry, including all trusted traveler and registered traveler programs. This system of records notice is being re-published to update the categories of records, authorities, purposes, routine uses, retrievability, retention and disposal, notification procedures, record sources, and exemptions sections of the system. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. The Global Enrollment System will now maintain law enforcement information as part of the vetting results, therefore the Department of Homeland Security is issuing a Notice of Proposed Rulemaking, to exempt this system of records from certain provisions of the Privacy Act of 1974, as amended, elsewhere in the **Federal Register**. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before February 15, 2013. This updated system will be effective February 15, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–0076 by one of the following methods:

• *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Fax:* 202–343–4010.

• *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Laurence Castelli, (202) 325–0280, CBP Privacy Officer, U.S. Customs and Border Protection, Mint Annex, 799 Ninth Street NW., Washington, DC 20229. For privacy questions, please contact: Jonathan R. Cantor, (202) 343–1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Customs and Border Protection (CBP) proposes to update and reissue a current DHS system of records titled, ''DHS/CBP–002 Global Enrollment System (GES).''

Global Entry (GE) is the DHS/CBP program that enables CBP to expedite the inspection and security process for lower risk travelers and allows more scrutiny for those travelers who present an unknown risk. GE, previously a pilot program, is now a permanent trusted traveler program (77 FR 5681 (Feb. 6, 2012)). Under GE, expedited processing into the United States and certain foreign countries will be expanded through a growing number of participating U.S. and foreign international airports and foreign partnerships. Through such partnerships, U.S. citizens and citizens of certain foreign countries will be able to apply for expedited processing at their respective airports.

CBP has signed a number of joint statements with foreign partners that provide the basic framework for allowing U.S. citizens and citizens of the applicable foreign countries to apply for expedited processing at their respective airports. The general purpose of the joint statement is to offer expedited processing to U.S. citizens and the citizens of the foreign country that is party to that joint statement, based on a mutually determined set of vetting criteria and standards. CBP continues to work with government border authorities in various countries to create this growing international network in which, once individuals are screened and deemed trusted by the authorities in their own country, the other country in the alliance will accept them in their respective national trusted traveler programs.

Depending on the nature of the agreement with the foreign partner, DHS/CBP will maintain and share different personally identifiable information. In certain instances the joint statements commit to allowing citizens of foreign countries to apply for GE after the appropriate Interconnectivity Service Agreement (ISA) has been implemented. In other instances, the joint statements commit to sharing information about citizens who apply to be members of both countries' trusted traveler program after the appropriate ISA has been implemented. As part of the procedures for implementing a joint statement and adding foreign partners to GE, CBP and each foreign partner are executing parallel protocols that incorporate privacy protections. A more in-depth discussion of the arrangements by country is made available in DHS/CBP/PIA—002(b) GES Privacy Impact Assessment and Appendix A ''CBP Global Entry Expansion: Joint Statements,'' which is being published in conjunction with this system of records and will be updated with relevant information.

In addition to new foreign partners, CBP has consolidated the registered traveler programs under GES to include the Small Vessel Reporting System (SVRS) and the Decal and Transponder Online Procurement System (DTOPS). SVRS, as an enhancement to the Local Boater Option (LBO) pilot program, allows individuals with advance submission and CBP approval of float plans to use a designated telephone line to notify a CBP officer of their arrival to the United States. DTOPS is a registered traveler program that allows individuals to purchase, renew, or transfer user fees related to the transponders/Radio Frequency Identification (RFID) tags for their commercial vehicles or to the decals for their private aircraft or vessels in advance of crossing a U.S. border.

This system of records notice is being re-published to update the categories of records, authorities, purposes, routine uses, retrievability, retention and disposal, notification procedures, record sources, and Privacy Act exemptions for this system of records. Specifically, DHS is updating the category of records to clarify that GES maintains limited law enforcement information, consisting of the case number references to law enforcement databases used to support or deny the membership decision for GES trusted traveler programs, as well as the membership decision for trusted traveler programs with foreign partners. These results were previously covered by the DHS/CBP—011 TECS SORN (73 FR 77778 (Dec. 19, 2008.)) In cases when the applicant has opted to share information with a foreign government trusted traveler program, DHS/CBP is also retaining other foreign governments' decisions either to approve or deny an application, pursuant to the applicable joint statements.

The authority for GES derives from CBP's mandate to secure the borders of the United States, and to facilitate legitimate trade and travel. The statutes that permit and define GES include:

• Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), as amended, 8 U.S.C. 1365b(k);

• Section 215 of the Immigration and Nationality Act, as amended, 8 U.S.C. 1185;

• Section 402 of the Homeland Security Act of 2002, as amended, 6 U.S.C. 202;

• Section 404 of the Enhanced Border Security and Visa Reform Act of 2002, 8 U.S.C. 1753; and

• Section 433 of the Tariff Act of 1930, as amended, 19 U.S.C. 1433.

The Regulations that permit and define GES include Parts 103 and 235 of Title 8 of the Code of Federal Regulations. See, especially, 8 CFR 103.2, 103.7, 103.16, 235.1, 235.2, 235.7, and 235.12. Pursuant to the Independent Offices Appropriations Act of 1952, 31 U.S.C. 9701, individuals seeking to enroll in trusted traveler or registered traveler programs must pay a fee when they apply or renew their membership. See 8 CFR 103.7(b)(1)(ii)(M).

The purposes of GES have been simplified to reflect that this system collects information, in advance, from recurring travelers so that DHS and CBP can assess applicants' eligibility for enrollment in a GES-supported trusted traveler and registered traveler programs.

DHS changed the order of routine uses to be consistent with its practice across all DHS SORNs and for ease of use by DHS personnel. This change affects the following uses, which were not substantially changed: Former routine use A is now routine use I;

former routine use B is now routine use G; former routine use C is now routine use B; former routine use D is now routine use C; former routine use E is now routine use A; and former routine use G is now routine use D.

This SORN update includes the following substantive changes to routine uses: In routine use F, the sentence has been added, ''Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.'' In routine use G, reference to ''organizations that are lawfully engaged in collecting intelligence [* * *] to carry out intelligence responsibilities'' has been removed because of redundancy. Routine use H has been added to provide additional transparency on the sharing with foreign governments for trusted traveler programs and only at the behest of the individual. Routine use L has been added to allow the Department to share information with the public when the interests of the public outweigh those of the individual and only after approval by the DHS Chief Privacy Officer in consultation with counsel.

Sharing GES information with partnering foreign countries is consistent with the routine uses proposed in this System of Records Notice (SORN), which allows for disclosure to foreign government agencies to elicit information necessary to make decisions on applications. Pursuant to CBP's reciprocal joint statements, CBP will share biographic GE application data and vetting results in the form of a ''pass/fail'' transmission of U.S. citizens with these foreign governments only upon receiving the same type of data from those governments on their citizens who are applying for expedited processing into the United States. Because of these international information sharing relationships, CBP is able to make well-informed decisions on GE applications of citizens from a growing number of countries.

The retrievability section has been updated to reflect that records may be retrieved by any of the personal identifiers listed in the categories of records.

The retention and disposal section has been updated to reflect that all GES data is retained for the duration of an individual's active membership plus three years after an individual's membership is no longer active, either as a result of expiration without renewal at the end of a five-year term, as a result of abandonment, or as a result of CBP termination.

The notification procedures section has been updated to provide notice that individuals may view and edit their information through their online accounts, as well as through the standard procedures under the Freedom of Information Act and Privacy Act.

The record source categories have been updated to clarify the records obtained from the individual and background checks of external law enforcement systems, as well as providing notice that GES collects from membership determinations about trusted traveler applicants from partnering foreign countries.

Participation in these programs is entirely voluntary. Joint Statements with foreign partners establish that each country's use of GES information for vetting will be consistent with applicable domestic laws and policies. Participants should be aware that when they submit their information to a foreign country, or agree to share their information with a foreign partner, the foreign country uses, maintains, retains, or disseminates their information in accordance with that foreign country's laws and privacy protections.

Consistent with DHS' information sharing mission, information stored in GES may be shared with other DHS components whose personnel have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, information may be shared with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

DHS/CBP is simultaneously issuing a notice of proposed rulemaking to exempt portions of the DHS/CBP—002 GES SORN from the Privacy Act requirements. Pursuant to 5 U.S.C. 552a(j)(2) of the Privacy Act, law enforcement related records, including the pointer information to other law enforcement databases that support the DHS/CBP membership decision, and the law enforcement risk assessment worksheet that have been created during the background check and vetting process, are exempt from 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5) and (e)(8); (f); and (g)(1). Pursuant to 5 U.S.C. 552a(k)(2), records created during the background check and vetting process are exempt from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). In addition, when a record contains information from other exempt systems of records, DHS/CBP will claim the same exemptions for that record as are claimed for the original systems of records, and will claim any additional exemptions that this notice delineates.

CBP will not assert any exemptions with regard to accessing or amending an individual's application data in a trusted or registered traveler program and/or final membership determination in the trusted traveler programs. However, this data may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified in the GES SORN. The Privacy Act requires that DHS maintain an accounting of such disclosures made pursuant to all routine uses. Disclosing the fact that a law enforcement and/or intelligence agency has sought particular records may affect ongoing law enforcement activity. As such, pursuant to 5 U.S.C. 552a(j)(2) and (k)(2), DHS will claim an exemption from (c)(3), (e)(8), and (g)(1) of the Privacy Act, as is necessary and appropriate to protect this information. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/CBP—002 Global Enrollment System (GES).

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)—002.

SYSTEM NAME:

DHS DHS/CBP—002 Global Enrollment System (GES).

SECURITY CLASSIFICATION:

Unclassified, Sensitive, For Official Use Only, Law Enforcement-Sensitive.

SYSTEM LOCATION:

Records are maintained at the CBP Headquarters in Washington, DC and field offices and maintained IT system named the Global Enrollment Systems.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who apply to use any form of automated or other expedited inspection for verifying eligibility to cross the border into the United States.

CATEGORIES OF RECORDS IN THE SYSTEM:

GES collects the following information on trusted travelers:

Biographic application data, including:

- Full name;
- Alias(es);
- Date of birth;
- Place of birth;
- Language preference;
- Gender;
- Current and former addresses;
- Telephone numbers;
- Country of citizenship;
- Alien registration number (if applicable);
- Employment history (if available);
- PASS ID or Trusted Traveler membership number;
- Countries visited in the last five years;
- Criminal history (provided by applicant);
- Parental or Legal Guardian permission (if 18 years or younger);
- Driver's license number;
- Issuing state or province of the applicant's Driver's License;
- Global Online Enrollment System (GOES) user name and password (password is maintained in an encrypted format); and
- Answers to security questions to reset password.

Vehicle or Vessel information, as appropriate, including:

- Flag and home port (where the vessel is foreign flagged);
- Name, registration number, and registration issuing state or province of the applicant's vessel;
- Make and model, year, color, VIN number, and license plate number of the vehicle; and
- Owner name, gender, and date of birth.

Biometric data, including:

- Fingerprints (collected and stored through DHS/USVISIT–0012 DHS Automated Biometric Identification System (IDENT) for future identity verification);
- Fingerprint Identification Number (FIN);
- Height;
- Eye color; and
- Facial photographs.

Information added by DHS/CBP:

- Pointer information to other law enforcement databases that support the DHS/CBP membership decision;
- Law Enforcement risk assessment worksheet;
- Pay.gov tracking number;
- GE membership decision in the form of a ''pass/fail;'' and
- Foreign government membership decisions in the form of a ''pass/fail.''

The following information is collected on SVRS registered travelers:

- Full name;
- Gender;
- Date of birth;
- Place of birth;
- Country of citizenship;
- Address;
- Contact telephone number;
- Alternate telephone number;
- Contact email address;
- Password;
- Document type & number (e.g. U.S. Passport, Permanent Resident Card, Birth Certificate, etc.), place of issue, and expiration date of document; and
- Vessel information including registration number, hull ID number, decal number, registered name, location where vessel is registered, and vessel description (e.g., length, type, manufacturer, model, year, hull colors, etc.).

The following information is collected about DTOPS registered travelers:

- Account name;
- Physical address;
- Shipping address;
- Pay.gov tracking number;
- FAST ID, if the conveyance's owner is C–TPAT/FAST approved;
- Conveyance model year;
- Conveyance manufacturer name;
- Conveyance identification numbers and information, which are specific to the type of conveyance (e.g., local registration number, an aircraft's tail number, Coast Guard ID number, vessel name);
- Contact name;
- Contact telephone number; and
- Contact email address.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), as amended, 8 U.S.C. 1365b(k); Section 215 of the Immigration and Nationality Act, as amended, 8 U.S.C. 1185; Section 402 of the Homeland Security Act of 2002, as amended, 6 U.S.C. 202; Section 404 of the Enhanced Border Security and Visa Reform Act of 2002, 8 U.S.C. 1753; and Section 433 of the Tariff Act of 1930, as amended, 19 U.S.C. 1433; 31 U.S.C. 9701; Parts 103 and 235 of Title 8 of the Code of Federal Regulations (See, especially, 8 CFR 103.2, 103.7, 103.16, 235.1, 235.2, 235.7, and 235.12).

PURPOSE(S):

The purpose of this system is to assess on an ongoing basis applicants' eligibility for enrollment in DHS/CBP GES-supported trusted traveler and/or registered traveler programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including U.S. Attorney Offices, or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS' efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To foreign governments, at the request of the individual, for the purpose of applying to that country's trusted traveler program.

I. To an appropriate federal, state, tribal, local, international, or foreign law enforcement agency for the purpose of determining an individual's eligibility for membership in a trusted traveler or registered traveler program.

J. To federal and foreign government intelligence or counterterrorism agencies or components where DHS becomes aware of an indication of a threat or potential threat to national or international security, or to assist in anti-terrorism efforts.

K. To an organization or person in either the public or private sector, either foreign or domestic, where there is a reason to believe that the recipient is or could become the target of a particular terrorist activity or conspiracy, or where the information is relevant to the protection of life, property, or other vital interests of a person.

L. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS' officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

RETRIEVABILITY:

Records may be retrieved by any of the personal identifiers listed in the categories of records above.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

CBP is proposing to NARA the following retention: All GES data is retained for the duration of an individual's active membership plus three years after an individual's membership is no longer active, either as a result of expiration without renewal at the end of a five year term, as a result of abandonment, or as a result of CBP termination.

SYSTEM MANAGER AND ADDRESS:

Trusted Traveler Program Manager, Office of Field Operations, U.S. Customs and Border Protection, and Director, Passenger Systems Program Office, Office of Information and Technology, 1300 Pennsylvania Ave. NW., Washington, DC 20229.

NOTIFICATION PROCEDURE:

Individuals may gain access to information on themselves in GES by directly logging into GOES. Certain information may be amended directly in the system by the individual such as contact information; however, other information that was used to determine eligibility, such as date of birth or gender, may not be changed without contacting DHS/CBP directly. The Secretary of Homeland Security has exempted portions of this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, DHS/CBP will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or CBP FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;

• Specify when you believe the records would have been created; and

• Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records; and

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records in GES are obtained from the individual and from external law enforcement systems. The main database checked during the vetting process, before individuals will be enrolled in any trusted traveler program, is TECS, which contains historical and enforcement data on travelers, and provides a gateway to other sources of data. These other sources include the Terrorist Screening Database, FBI criminal history, and National Crime and Information Center outstanding wants/warrants, vehicle and driver's license-related data contained in the International Justice and Public Safety Network's Nlets system, and Department of State alien records, lookouts, and status indicators. Vetting results are also based on checks of the FBI's Integrated Automated Fingerprint Identification System for criminal history and IDENT for immigration related records. Trusted traveler applicants from partnering foreign countries will have membership determinations in GES from their home country's government.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2) has exempted the law enforcement related records, including the pointer information to other law enforcement databases that support the DHS/CBP membership decision, and the law enforcement risk assessment worksheet that have been created during the background check and vetting process, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5) and (e)(8); (f); and (g)(1). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted records created during the background check and vetting process from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H),(e)(4)(I); and (f). In addition, when a record contains information from other exempt systems of records, DHS/CBP will claim the same exemptions for that record as are claimed for the original systems of records, and will claim any additional exemptions that this notice delineates.

CBP will not assert any exemptions with regard to accessing or amending an individual's application data in a trusted or registered traveler program and/or final membership determination in the trusted traveler programs. However, this data may be shared with law enforcement and/or intelligence agencies pursuant to the routine uses identified in the GES SORN. The Privacy Act requires DHS maintain an accounting of such disclosures made pursuant to all routine uses. Disclosing the fact that a law enforcement and/or intelligence agency has sought particular records may affect ongoing law enforcement activity. As such, pursuant to 5 U.S.C. 552a (j)(2) and (k)(2), DHS will claim an exemption from (c)(3), (e)(8), and (g)(1) of the Privacy Act, as is necessary and appropriate to protect this information.

Dated: December 31, 2012.

Jonathan R. Cantor,

Acting Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2013–00804 Filed 1–15–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–MB–2012–N302; FF09M21200–134–FXMB1231099BPP0]

Migratory Bird Hunting; Service Regulations Committee Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The Fish and Wildlife Service (hereinafter Service) will conduct an open meeting on February 6, 2013, to identify and discuss preliminary issues concerning the 2013–14 migratory bird hunting regulations.

DATES: The meeting will be held February 6, 2013.

ADDRESSES: The Service Regulations Committee meeting will be available to the public in conference room 2073 at 4501 N. Fairfax Street, Arlington, VA. 22203.

FOR FURTHER INFORMATION CONTACT: Chief, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, ms-4107–ARLSQ, 1849 C Street NW., Washington, DC 20240; (703) 358–1714.

SUPPLEMENTARY INFORMATION: Under the authority of the Migratory Bird Treaty Act (16 U.S.C. 703–712), the Service regulates the hunting of migratory game birds. We update the migratory game bird hunting regulations, located at 50 CFR part 20, annually. Through these regulations, we establish the frameworks, or outside limits, for season lengths, bag limits, and areas for migratory game bird hunting. To help us in this process, we have administratively divided the nation into four Flyways (Atlantic, Mississippi, Central, and Pacific), each of which has a Flyway Council. Representatives from the Service, the Service's Migratory Bird Regulations Committee, and Flyway Council Consultants will meet on February 6, 2013, at 11:00 a.m. to identify preliminary issues concerning the 2013–14 migratory bird hunting regulations for discussion and review by the Flyway Councils at their March meetings.

In accordance with Department of the Interior (hereinafter Department) policy regarding meetings of the Service Regulations Committee attended by any person outside the Department, these meetings are open to public observation.

Dated: January 3, 2013.

Michael J. Johnson,

Acting Assistant Director, Migratory Birds, U.S. Fish and Wildlife Service.

[FR Doc. 2013–00784 Filed 1–15–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTB07900 09 L10100000 PH0000 LXAMANMS0000]

Notice of Public Meeting; Western Montana Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Western

Montana Resource Advisory Council (RAC) will meet as indicated below.

DATES: The meeting will be held February 20, 2013. The meeting will begin at 9 a.m. with a 30-minute public comment period starting at 11:30 a.m. and will adjourn at 3 p.m.

ADDRESSES: The meeting will be in the BLM's Butte Field Office, 106 N. Parkmont, in Butte, Montana.

SUPPLEMENTARY INFORMATION: This 15-member council advises the Secretary of the Interior on a variety of management issues associated with public land management in Montana. During this meeting the council will participate in/discuss/act upon several topics, including a discussion of proposed fees for the historic Henneberry Homestead near Dillon, and updates from the BLM's Butte, Missoula and Dillon field offices.

All RAC meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

FOR FURTHER INFORMATON CONTACT: David Abrams, Western Montana Resource Advisory Council Coordinator, Butte Field Office, 106 North Parkmont, Butte, MT 59701, 406–533–7617, *dabrams@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Richard M. Hotaling,

District Manager, Western Montana District.

[FR Doc. 2013–00829 Filed 1–15–13; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Number 1010–0181]

Information Collection: Southern Alaska Sharing Network and Subsistence Study; Submitted for OMB Review; Comment Request

ACTION: 30-day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is notifying the public that we have submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval. The ICR pertains to conducting a survey on subsistence and sharing networks in coastal Alaska. This notice provides the public a second opportunity to comment on the paperwork burden of this collection.

DATES: Submit written comments by February 15, 2013.

ADDRESSES: Submit comments on this ICR to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_submission@omb.eop.gov* (email). Please provide a copy of your comments to the BOEM Information Collection Clearance Officer, Arlene Bajusz, Bureau of Ocean Energy Management, 381 Elden Street, HM–3127, Herndon, Virginia 20170 (mail) or *arlene.bajusz@boem.gov* (email). Please reference ICR 1010–0181 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Arlene Bajusz, Office of Policy, Regulations, and Analysis at *arlene.bajusz@boem.gov* (email) or (703) 787–1025 (phone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1010–0181.

Title: Southern Alaska Sharing Network and Subsistence Study.

Abstract: The Bureau of Ocean Energy Management (BOEM), under the Department of the Interior (DOI), is the Federal administrative agency that conducts OCS lease sales and monitors and mitigates adverse impacts that might be associated with offshore resource development. Within BOEM, the Environmental Studies Program implements and manages the responsibilities of research. This study will facilitate the meeting of DOI/BOEM information needs on subsistence food harvest and sharing activities in various coastal Alaska areas.

Planning areas for potential resource development in Alaska can include large geographic areas with diverse, abundant, and environmentally sensitive resources. Within these areas, the DOI's Proposed OCS Oil and Gas Leasing Program considers that there will be an oil and gas lease sale in the future. These proposed sale areas or adjacent areas support major productive commercial and subsistence fisheries; provide habitat to numerous marine mammals and land animals, as well as plant harvesting; and are a significant migration and staging area for internationally important waterfowl. Numerous communities in the State of Alaska rely heavily on subsistence fisheries.

This study assesses the vulnerabilities of several coastal communities in southern Alaska as to the potential effects of offshore oil and gas development on subsistence food harvest and sharing activities. It investigates the resilience of local sharing networks that structure contemporary subsistence-cash economies using research methods that involve the residents of these communities most proximate to the future sale area(s).

The BOEM will use the information collected to gain knowledge about local social systems that will help shape development leasing strategies and serve as an interim baseline for impact monitoring to compare against future research in these areas. Without this data, BOEM will not have sufficient information to make informed leasing and development decisions for these areas.

Survey Instrument: The research will be collected from a survey administered to each head of household in the communities to collect information about the subsistence (harvest data) and sharing networks of the communities. The information under this collection will be obtained through personal interviews that are voluntary.

Interview Methods: The interviews for each study will be conducted in person in a setting most comfortable for the respondents. This personal method is more expensive and time consuming for the researchers, but these drawbacks are outweighed by improvements in the quality of information obtained and the rapport established. Telephone interviews have not been successful in rural Alaska. Each respondent will be paid an honorarium for taking part in the study. Responses are voluntary and confidential.

Frequency: One-time event for each study.

Description of Respondents: Approximately 548 respondents from southern Alaska coastal communities.

Estimated Reporting and Recordkeeping Hour Burden: The estimated annual hour burden for this collection is 411 hours. We estimate each survey will take about 45 minutes.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified no non-hour cost burdens for this collection.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501, *et seq.*) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *'' Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

To comply with the public consultation process, on August 22, 2012, BOEM published a **Federal Register** notice (77 FR 50712) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. We received one comment. The Marine Mammal Commission commended BOEM for including science-based assessments of subsistence food harvest and sharing activities in Alaskan communities as part of its Environmental Studies Program and therefore supports the collection of information. Comments are accepted at any time.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 6, 2012.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations, and Analysis.

[FR Doc. 2013–00763 Filed 1–15–13; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for the requirements for permits and permit processing has been submitted to the Office of Management and Budget (OMB) for review and approval. The information collection package was previously approved and assigned control number 1029–0115. This information collection will also seek approval to collect permit processing fees approved under OSM regulations.

This notice describes the nature of the information collection activity and the expected burdens.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by February 15, 2013, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0115 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted a request to OMB to renew its approval for the collection of information for 30 CFR Part 773—Requirements for Permits and Permit Processing. OSM is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection, 1029–0115, is listed in 30 CFR 773.3. Individuals are required to respond to obtain a benefit.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on these collections of information was published on October 3, 2012 (77 FR 60459). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following collection activity:

Title: 30 CFR Part 773—Requirements for Permits and Permit Processing.

OMB Control Number: 1029–0115.

Summary: The collection activities for this Part ensure that the public has the opportunity to review permit applications prior to their approval, and that applicants for permanent program permits or their associates who are in violation of the Surface Mining Control and Reclamation Act do not receive surface coal mining permits pending resolution of their violations. This collection request includes the submission of processing fees authorized by 30 CFR 736.25 and 750.25 in Federal program states and on Indian lands, respectively.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for surface coal mining and reclamation permits and State governments and Indian Tribes.

Total Annual Respondents: 892 coal mining applicants and 24 regulatory authorities.

Total Annual Burden Hours: 38,442.

Total Annual Non-Wage Cost Burden: $108,520.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the

information, to the places listed in Addresses. Please refer to control number 1029–0115 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment-including your personal identifying information-may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 27, 2012.

Andrew F. DeVito,

Chief, Division of Regulatory Support.

[FR Doc. 2013–00614 Filed 1–15–13; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1205 (Preliminary)]

Silica Bricks and Shapes From China

Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (Commission) determines, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) (the Act), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from China of silica bricks and shapes, provided for in subheading 6902.20.10 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (LTFV).

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigation. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (Commerce) of an affirmative preliminary determination in the investigation under section 733(b) of the Act, or, if the preliminary determination is negative, upon notice of an affirmative final determination in that investigation under section 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigation need not enter a separate appearance for the final phase of the investigation. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

Background

On November 15, 2012, a petition was filed with the Commission and Commerce by Utah Refractories Corp., Lehi, UT, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of silica bricks and shapes from China. Accordingly, effective November 15, 2012, the Commission instituted antidumping duty investigation No. 731–TA–1205 (Preliminary).

Notice of the institution of the Commission's investigation and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 23, 2012 (77 FR 70185). The conference was held in Washington, DC, on December 6, 2012, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on December 31, 2012. The views of the Commission are contained in USITC Publication 4369 (January 2013), entitled *Silica Bricks and Shapes from China: Investigation No. 731–TA–1205 (Preliminary).*

By order of the Commission.

Issued: January 10, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–00741 Filed 1–15–13; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–781]

Certain Microprocessors, Components Thereof, and Products Containing Same; Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge has issued a Final Initial Determination and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation of section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. 1337, specifically a limited exclusion order, and cease and desist orders against certain respondents.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on December 14, 2012. In that determination, the administrative law judge recommended that should the Commission find a violation of section 337, that the Commission issue a limited exclusion order as to subject Intel microprocessors, but that implementation be delayed based on public-interest considerations. The ALJ recommended against extension of the exclusion order to cover downstream products produced by respondents Apple and Hewlett-Packard. The ALJ recommended that cease and desist orders issue against Intel, Apple, and HP.

Comments should address whether issuance of a limited exclusion order and cease and desist orders in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the limited exclusion order and cease and desist orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on January 25, 2013.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–753'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.

Issued: January 10, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–00764 Filed 1–15–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[FCSC Meeting and Hearing Notice No. 1–13]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Friday, January 25, 2013: 10:00 a.m.—Oral hearings on Objection to Commission's Proposed Decisions in Claim No. LIB–II–183; 11:00 a.m.—Claim No. LIB–II–058;

11:30 a.m.—Issuance of Proposed Decision in claims against Libya;

1:00 p.m.—Oral hearings on Objection to Commission's Proposed Decision in Claim No.—LIB–II–166.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Judith H. Lock, Executive Officer, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975.

Jeremy R. LaFrancois,

Chief Administrative Counsel.

[FR Doc. 2013–00953 Filed 1–14–13; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement: Development of Materials Specific to Lesbian, Gay, Bisexual, Transgender and Intersex (LGBTI) Offenders in Corrections

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is seeking applications from organizations, groups, or individuals to enter into a cooperative agreement with NIC for a 12-month period to develop a white paper specific to recommended best practices in the safe and respectful management of the LGBTI offender population both in custody and on community supervision.

DATES: Applications must be received by 4:00 p.m. (EDT) on Thursday, January 31, 2013.

Applicants are encouraged to submit their application electronically via *http://www.grants.gov.*

Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street NW., Room 5002, Washington, DC 20534. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date.

Faxed or emailed applications will not be accepted.

FOR FURTHER INFORMATION: A copy of this announcement and links to the required application forms can be downloaded from the NIC Web site at *http://www.nicic.gov/cooperative agreements.*

All technical or programmatic questions concerning this announcement should be directed to Lorie Brisbin, Correctional Program Specialist, National Institute of Corrections, Community Services Division. Ms. Brisbin can be reached directly at 1–800–995–6423 ext. 40099 or by email at *lbrisbin@bop.gov.* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

SUPPLEMENTARY INFORMATION:

Overview: The materials developed through this cooperative agreement are intended for a broad audience of corrections professionals and related stakeholders working in jail, prison, juvenile detention, and community corrections (probation, parole and pretrial) organizations. Awardees should develop the materials based on current research, knowledge, best practice, and specific information related to the experiences of corrections professionals and the target population. NIC will use the materials to define, identify, acknowledge, and address the safe and respectful management of the LGBTI offender. The deliverables will help advance and foster professional correctional environments while positively influencing systems, staff, and justice-involved men and women.

Background: The National Institute of Corrections provides support to federal, state, and local criminal justice organizations nationally. In 1974, Congress established NIC both as a center for the dissemination of timely correctional knowledge and professional training and as a place to exchange and discuss advances in criminal justice practice. Correctional agencies face many challenges surrounding the safe management of the populations they house and supervise. Due in part to changes in federal and state laws and the outcome of successful offender litigation, the management of LGBTI offenders in custody has become an emerging correctional issue that deserves special attention. While gender non-conforming offenders have always been present within correctional facilities and on caseloads, the current environment suggests the need for helping correctional agencies identify responsible and safe practices that are respectful of differences and that have the potential to reduce agencies' susceptibility to liability and litigation.

In the past several years, various changes to federal and state laws have created and expanded the rights of individuals identifying as non-heterosexual or otherwise gender non-conforming. The repeal of the policy banning military staff from serving as openly gay (''Don't Ask, Don't Tell''), the expansion of protections under hate crime and housing laws, and the adoption of same-sex marriage laws are a few examples of some of these changes. While it is unclear how many of the free-world rights and privileges will affect the offender population, the promulgation of the Prison Rape Elimination Act Standards is beginning to have an impact regarding the management of the LGBTI population.

The LGBTI offender population has some very particular issues associated with certain aspects of the correctional experience, such as housing, classification, and placement; medical and mental health treatment; clothing and grooming; drug testing; and interactions with staff. As a general group, they are also more likely to be victims of sexually abusive acts while in custody according to surveys conducted by the Bureau of Justice Statistics (BJS), which indicate that non-heterosexual adult offenders report higher rates of sexual victimization while in custody. Similar surveys by BJS in juvenile facilities show even higher rates of sexual victimization among non-heterosexual juvenile offenders. Similarly, a 2009 BJS research report cited findings that transgender offenders experienced sexual victimization at a rate twenty times higher than a random sampling of offenders in the same facility.

Unfortunately, there is a remarkable lack of research regarding the LGBTI population's experience of incarceration and supervision. There are a number of reasons for this. Most notably, it is because few agencies collect data regarding sexual orientation and the hesitation of offenders to provide the information. Consequently, it is unclear how many offenders identify as non-heterosexual or otherwise gender non-conforming. A recent report from the Bureau of Justice Statistics indicates that there were 2,239,800 individuals in custody in prisons and jails and 4,814,200 on probation or parole for 2011. A Gallup report published in October 2012 by the Williams Institute reported that 3.4% of US adults identify as lesbian, gay, bisexual or transgender. Therefore, a conservative estimate could be made based upon this 3.4%, indicating that there could potentially have been 76,153 non-heterosexual offenders in custody and as many as 163,682 on probation or parole for 2011. However, a Bureau of Justice Statistics study in 2006 contained self-report data for in-custody offenders indicating that 11% in men's facilities and 28% in women's facilities identified as lesbian, gay, or bisexual, so the number may be considerably higher.

Statement of Work: The objective of this cooperative agreement is to develop informational materials reflecting best practices that NIC will use to assist the field in responding to challenges associated with the LGBTI offender population.

Activities and products from this cooperative agreement will include a review of the NIC annotated bibliography to identify additional items for inclusion in that publication, the convening and facilitating of a work session comprised of researchers and practitioners (both correctional and non-correctional) to organize and synthesize the available research and knowledge on this topic, and the development of informational materials to be determined by content. Resulting products will be in the public domain and available through the National Institute of Corrections Web site and Information Center.

Tasks to be performed through this cooperative agreement include: (1) Reviewing the current annotated bibliography, conducting a literature search, and providing recommendations for the inclusion of additional materials relevant to jails, prisons, juvenile detention, community corrections, and other relevant disciplines. (2) convening a working session at an approved federal training location for up to 10 participants, including researchers and corrections practitioners; designing the working agenda; providing facilitation; and using content from the session to inform project deliverables. Working session participants will be identified in close cooperation with and with the approval of the project staff. Some travel expenses may be covered by NIC and therefore are negotiable depending on the meeting and/or successful applicant's location. (3) working with NIC project staff, and designated experts to draft informational materials reflecting best practices on the safe and respectful management of LGBTI offenders both in custody and on supervision; distributing the materials for peer review; revising the draft; and publishing the final products. (4) creating a final report that summarizes the project and provides recommendations for follow up work on this topic. This project will be

completed in conjunction with the NIC Community Services Division and the awardee will work closely with NIC staff on all aspects of the project. The awardee will participate in an initial meeting with designated NIC staff for a project overview and preliminary planning. Additionally, the awardee will meet routinely with NIC staff to discuss the activities noted in the project timeline submitted during the course of the cooperative agreement. Meetings will be held no less than quarterly and may be conducted via webinar with at least one onsite as agreed upon by NIC and the awardee.

Required Expertise: The successful applicant will at a minimum understand the current state of legislation regarding LGBTI rights in the free world as well as current case law affecting the LGBTI in-custody population; have broad experience and in-depth knowledge of the issues encountered by correctional agencies in the management of this population, whether working in an institutional environment or community-based setting; have knowledge about the effect of correctional culture and the challenges in maintaining a professional and respectful environment; be familiar with relevant research; have expertise in meeting facilitation; and have knowledge of evidence-based practices and its application to corrections.

Document Requirements: The length of documents should be determined by content. Brevity and clarity are encouraged. Documents and other products developed under this award must follow these guidelines. Prior to the preparation of the final draft of any document or other product, the awardee must consult with NIC's writer/editor concerning the acceptable formats for submissions. The awardee must follow the guidelines listed herein as well as follow (1) the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements* and (2) NIC recommendations for producing products using plain language, which can be found at *www.nicic.gov/plainlanguage.*

All final documents and other materials submitted under this project may be posted on the NIC Web site and must meet the federal government's requirement for accessibility (e.g., 508 PDFs or HTML files). The awardee must provide descriptive text interpreting all graphics, photos, graphs, and/or multimedia that will be included with or distributed alongside the materials and must provide transcripts for all applicable audio/visual works.

Application Requirements: An application package must include OMB Standard Form 424, Application for Federal Assistance; a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year under which the applicant operates (e.g. July 1 through June 30); an outline of projected costs with the budget and strategy narratives described in the announcement. The following additional forms must also be included: OMB Standard Form 424A, Budget Information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (both available at www.grants.gov); DOJ/FBOP/NIC Certification Regarding Lobbying, Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://www.nicic.gov/Downloads/General/certif-frm.pdf.*

Applications should be concisely written, typed double spaced, and reference the NIC opportunity number and title referenced in this announcement. If you are submitting in hard copy, please include an original and three copies of your full proposal (program and budget narrative, application forms, assurances, and other descriptions). The original should have the applicant's signature in blue ink. Electronic submissions will be accepted only via *www.grants.gov.*

Place the following at the top of the abstract: Project title; Applicant name (Legal name of applicant organization); Mailing address; Contact phone numbers (voice, fax); Email address; Web site address, if applicable.

The narrative portion of the application should include, at a minimum: A statement indicating the applicant's understanding of the project's purpose and objectives. The applicant should state this in language other than that used in the solicitation.

Project Design and Implementation: This section should describe the design and implementation of the project and how the awardee aims to address key design and implementation issues and challenges.

Project Management: Chart of measurable project milestones and timelines for the completion of each milestone.

Capabilities and Competencies: This section should describe the qualifications of the applicant organization, any partner organizations to do the work proposed, and the expertise of key staff to be involved in the project. Attach resumes that document relevant knowledge, skills, and abilities needed for each staff member assigned to complete the project. If the applicant organization has completed similar projects in the past, please include the URL/Web site or ISBN number for accessing a copy of the referenced work.

Budget: The budget should detail all costs for the project, show consideration for all contingencies for the project, note a commitment to work within the proposed budget, and demonstrate the ability to provide deliverables according to schedule.

Authority: Pub. L. 93–415.

Funds Available: NIC is seeking the applicant's best ideas regarding accomplishment of the scope of work and the related costs for achieving the objectives of this solicitation. Funds may be used only for the activities linked to the desired outcome of the project. The funding amount should not exceed $30,000 for a period of 12 months.

Eligibility of Applicants: An eligible applicant is any state or general unit of government, private agency, educational institution, organization, individual, or team with expertise in the described areas. Applicants must have demonstrated ability to implement a project of this size and scope.

Review Considerations: Among the criteria used to evaluate the applications are indication of a clear understanding of the project requirements as stated in the solicitation; background, experience, and expertise of the proposed project staff, including any sub-contractors; effectiveness of an innovative approach to the project; a clear, concise description of all elements and tasks of the project, with sufficient and realistic timeframes necessary to complete the tasks; technical soundness of project design and methodology; financial and administrative integrity of the proposal, including adherence to federal financial guidelines and processes; a sufficiently detailed budget that shows consideration of all contingencies for this project and commitment to work within the proposed budget; and indication of availability to work with NIC staff.

Applications received under this announcement will be subject to a collaborative review process. The criteria for the evaluation of each application will be as follows:

Programmatic: 40 Points

Are all of the tasks and activities adequately covered? Is there a clear description of how the applicant will

accomplish each project activity, including major tasks; the strategies to be employed; required staffing; responsible parties, and other required resources? Are there any unique or exceptional approaches, techniques, or design aspects proposed that will enhance the project?

Project Management and Administration: 20 Points

Does the applicant identify milestones and measures that demonstrate achievement of the specific tasks? Are the proposed management and staffing plans clear, realistic, and sufficient to complete the project? Is the applicant willing to meet with NIC as specified in the solicitation for this cooperative agreement?

Organizational and Project Staff Background: 30 Points

Do the skills, knowledge, and expertise of the organization and the proposed project staff demonstrate a high level of competency to complete the tasks? Does the applicant/organization have the necessary experience and organizational capacity to meet all objectives of the project? If the applicant proposes consultants and/or partnerships, is there a reasonable justification for their inclusion in the project and a clear structure to ensure effective coordination?

Budget: 10 Points

Is the proposed budget realistic, does it provide sufficient cost detail/narrative, and does it represent good value relative to the anticipated results? Does the application include a chart that aligns the budget with project activities along a timeline with, at minimum, quarterly benchmarks? In terms of program value, is the estimated cost reasonable in relation to the work to be performed and project products?

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

Applicants can obtain a DUNS number at no cost by calling the dedicated toll-free request line at 800–333–0505. Applicants who are sole proprietors should dial 866–705–5711 and select option #1.

Applicants may register in the CCR online at the CCR Web site: *www.ccr.gov.* Applicants can also review a CCR handbook and worksheet at this Web site.

Number of Awards: One

NIC Opportunity Number: 13CS06. This number should appear as a reference line in the cover letter, where indicated on Standard Form 424, and outside of the envelope in which the application is sent.

Catalog of Federal Domestic Assistance Number: 16.601.

Executive Order 12372: This project is not subject to the provisions of Executive Order 12372.

Robert Brown, Jr.,

Acting Director, National Institute of Corrections.

[FR Doc. 2013–00846 Filed 1–15–13; 8:45 am]

BILLING CODE 4410–36–P

NATIONAL CAPITAL PLANNING COMMISSION

Public Comment and Public Meeting on Draft Revisions to the Visitors Element of the Comprehensive Plan for the National Capital: Federal Elements

AGENCY: National Capital Planning Commission.

ACTION: Notice of public comment period and public meeting.

SUMMARY: The National Capital Planning Commission (NCPC), the Planning Commission for the Federal Government within the National Capital Region, intends to release for public comment draft revisions to the Federal Visitors and Commemorative Works Element of the Comprehensive Plan for the National Capital: Federal Elements. The Comprehensive Plan for the National Capital: Federal Elements addresses matters relating to Federal Properties and Federal Interests in the National Capital Region, and provides a decision-making framework for actions the NCPC takes on specific plans and proposals submitted by Federal government agencies for the NCPC review required by law. The Federal Visitors and Commemorative Works Element articulates policies that guide federal actions on supporting visitor services to the National Capital Region as well as guiding actions related to commemoration. The draft revised Federal Visitors and Commemorative Works Element will be available online at *http://www.ncpc.gov/compplan* by Monday, January 14, 2013. Printed copies are available upon request from the contact person noted below.

DATES AND TIME: The public comment period begins on the date of publication of this notice and closes on Friday, March 15, 2013. A public meeting to discuss the draft revisions to the Federal Environment Element will be held on Wednesday, February 20, 2013 from 6:30 p.m.–8:30 p.m.

ADDRESSES: Mail written comments or hand deliver comments on the draft revisions to Comprehensive Plan Public Comment, National Capital Planning Commission, 401 9th Street NW., Suite 500, Washington, DC 20004. The public meeting will be held at 401 9th Street NW., North Lobby, Suite 500, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: David Zaidain at (202) 482–7230 or *david.zaidain@ncpc.gov.* Please confirm meeting attendance with Mr. Zaidain or as noted below.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing Addresses

You may submit comments electronically at the public comment portal at *http://www.ncpc.gov/compplan.*

Authority: (40 U.S.C. 8721(e)(2)).

Dated: January 10, 2013.

Anne R. Schuyler,

General Counsel.

[FR Doc. 2013–00824 Filed 1–15–13; 8:45 am]

BILLING CODE 7520–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Establish an Information Collection System

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501 et seq.), and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation (NSF) is inviting the general public or other Federal agencies to comment on this proposed continuing information collection.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility; (b) the accuracy of the Foundation's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

DATES: Written comments on this notice must be received by March 18, 2013, to

be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Ms. Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for the Emerging Frontiers in Research and Innovation program.

OMB Number: 3145–NEW.

Expiration Date of Approval: Not applicable.

Type of Request: Intent to seek approval to establish an information collection system.

Abstract

Proposed Project

The Emerging Frontiers in Research and Innovation (EFRI) program recommends, prioritizes, and funds interdisciplinary initiatives at the emerging frontier of engineering research and education. These investments represent transformative opportunities, potentially leading to: New research areas for NSF, ENG, and other agencies; new industries or capabilities that result in a leadership position for the country; and/or significant progress on a recognized national need or grand challenge.

Established in 2007, EFRI supports cutting-edge research that is difficult to fund through other NSF programs, such as single-investigator grants or large research centers. EFRI seeks high-risk opportunities with the potential for a large payoff where researchers are encouraged to stretch beyond their ongoing activities. Based on input from workshops, advisory committees, technical meetings, professional societies, research proposals, and suggestions from the research community the EFRI program identifies those emerging opportunities and manages a formal process for funding their research. The emerging ideas tackled by EFRI are ''frontier'' because they not only push the understood limits of engineering but actually overlap multiple fields. The EFRI funding process inspires investigators with different expertise to work together on one emerging concept.

EFRI awards require multi-disciplinary teams of at least one Principal Investigator and two Co-Principal Investigators. The anticipated duration of all awards is 4-years. The anticipated funding level for each project team may receive support of up to a total of $2,000,000 spread over four years, pending the availability of funds. In that sense EFRI awards are above the average single-investigator award amounts.

EFRI-funded projects could include research opportunities and mentoring for educators, scholars, and university students, as well as outreach programs that help stir the imagination of K–12 students, often with a focus on groups underrepresented in science and engineering.

We are seeking to collect additional information from the grantees about the outcomes of their research that goes above and beyond the standard reporting requirements used by the NSF and spans over a period of 5 years after the award. This data collection effort will enable program officers to longitudinally monitor outputs and outcomes given the unique goals and purpose of the program. This is very important to enable appropriate and accurate evidence-based management of the program and to determine whether or not the specific goals of the program are being met.

Grantees will be required to submit this information on an annual basis to support performance review and the management of EFRI grants by EFRI officers. EFRI grantees will be required to submit these indicators to NSF via a data collection Web site that will be embedded in NSF's IT infrastructure. These indicators are both quantitative and descriptive and may include, for example, the characteristics of project personnel and students; sources of complementary cash and in-kind support to the EFRI project; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; descriptions of significant advances and other outcomes of the EFRI effort. Such reporting requirements will be included in the cooperative agreement which is binding between the academic institution and the NSF.

Each submission will address the following major categories of activities: (1) Knowledge transfer across disciplines, (2) innovation of ideas in areas of greater opportunity, (3) potential for translational research, (4) project results advance the frontier/creation of new fields of study, (5) innovative research methods or discoveries are introduced to the classroom, and (6) fostering participation of underrepresented groups in science.

For each of the categories the report will enumerate specific outputs and outcomes.

Use of the Information: The data collected will be used for NSF internal reports, historical data, performance review by peer site visit teams, program level studies and evaluations, and for securing future funding for continued EFRI program maintenance and growth.

Estimate of Burden: Approximately 10 hours per grant for approximately 80 grants per year for a total of 800 hours per year.

Respondents: Principal Investigators who lead the EFRI grants.

Estimated Number of Responses per Report: One report collected for each of the approximately 80 grantees every year.

Dated: January 11, 2013.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2013–00765 Filed 1–15–13; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–10; NRC–2013–0002]

Prairie Island, Independent Spent Fuel Storage Installation; Notice of Docketing of Amendment Request to Special Nuclear Materials License No. 2506 Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request and opportunity to request a hearing and petition for leave to intervene; order.

DATES: Requests for a hearing or petition for leave to intervene must be filed by March 18, 2013. Any potential party as defined in section 2.4 of Title 10 of the Code of Federal Regulations (10 CFR), who believes access to Sensitive Unclassified Non-Safeguards Information (SUNSI) is necessary to respond to this document must request document access by January 28, 2013.

ADDRESSES: Please refer to Docket ID NRC–2013–0002 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC

possesses and are publically available, by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0002.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–492–3148; email: *William.Allen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) received, by letter dated June 18, 2012, as supplemented October 24, November 9 and November 13, 2012, a license amendment application from Northern States Power Company (NSPM), requesting a revision to the Technical Specifications of the TN–40HT cask utilized at its Prairie Island independent spent fuel storage installation located in Welch, Minnesota. License No. 2506 authorizes the licensee to receive, store, and transfer spent fuel from Prairie Island Nuclear Station Units 1 and 2. Specifically, the amendment seeks to lower the allowed thermal conductance of the neutron absorber and aluminum 1100 plate utilized in the TN–40HT cask from 3.98 BTU/hr-deg F to 3.55 BTU/hr-deg F.

An NRC administrative review, documented in a letter to NSPM dated November 15, 2012, found the application acceptable to begin a technical review. If the NRC approves the amendment, the approval will be documented in an amendment to NRC License No. 2506. However, before approving the proposed amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations. These findings will be documented in a Safety Evaluation Report. The NRC will also make findings consistent with the National Environmental Policy Act (NEPA) and 10 CFR Part 51.

II. Opportunity To Request a Hearing and Petitions for Leave To Intervene

Requirements for hearing requests and petitions for leave to intervene are found in 10 CFR 2.309, ''Hearing requests, petitions to intervene, requirements for standing, and contentions.'' Interested persons should consult 10 CFR 2.309, which is available at the NRC's PDR, located at O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852 or call the PDR at 1–800–397–4209 or 301–415–4737. The NRC's regulations are also accessible electronically from the NRC Library on the NRC's public Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

Any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings the NRC must make to support the granting of a license amendment in response to the application. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC's regulations, policies, and procedures. The Atomic Safety and Licensing Board (the Licensing Board) will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Requests for hearing, petitions for leave to intervene, and motions for leave to file contentions new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1) and (2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by March 18, 2013. The petition must be filed in accordance with the filing instructions in Section III of this document, and

should meet the requirements for petitions for leave to intervene set forth in this section, except that under 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance under 10 CFR 2.315(a), by making an oral or written statement of his or her position on the issues at any session of the hearing or at any pre-hearing conference, within the limits and conditions fixed by the presiding officer. However, that person may not otherwise participate in the proceeding.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC's guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Standard Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to

copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention in conformity with 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmail center@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions no later than that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, the normal process for litigating disputes concerning access to information apply, and not these procedures. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 10th day of January 2013.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's E-Filing Rule, 10 CFR 2.302, 2.304–2.305, see 72 FR 49139 (August 28, 2007), the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule, 10 CFR 2.302, 2.304–2.305, see 72 FR 49139 (August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2013–00793 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–302; NRC–2013–0005]

Florida Power Corporation, Crystal River Unit 3, Draft Environmental Assessment Related to the Proposed License Amendment To Increase the Maximum Reactor Power Level

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft environmental assessment and finding of no significant impact; opportunity to comment.

DATES: Comments must be filed by February 15, 2013. Any potential party as defined in section 2.4 of Title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to Sensitive Unclassified Non-Safeguards Information and/or Safeguards Information is necessary to respond to this notice must request document access by January 28, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publically available, by searching on *http://www.regulations.gov* under Docket ID NRC–2013–0005. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0005. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Siva P. Lingam, Project Manager, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1564; email: *Siva.Lingam@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2013–0005 when contacting the NRC about the availability of information regarding this document. You may access information related to this document by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0005.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each

document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The application for amendment, dated June 15, 2011 (ADAMS Accession No. ML112070659), contains proprietary information in Attachment 5 of the amendment and accordingly, those portions are being withheld from public disclosure. A redacted version of the application for amendment is available electronically as Attachment 7 of the amendment under ADAMS Accession No. ML11207A444.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0005 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment for Facility Operating License No. DPR–72, issued to Florida Power Corporation., (FPC, the licensee) for operation of the Crystal River Unit 3 Nuclear Power Plant (CR–3), for a license amendment to increase the maximum thermal power level from 2,609 megawatts thermal (MWt) to 3,014 MWt. In accordance with section 51.21 of Title 10 of the *Code of Federal Regulations* (10 CFR), the NRC has prepared this Draft Environmental Assessment (EA) documenting its finding. The NRC concluded that the proposed actions will have no significant environmental impact.

The proposed power increase is 15.52 percent over the current licensed thermal power. In 2002, the licensee received approval from the NRC to increase its power by 0.9 percent, and another approval in 2007, to increase its power by 1.6 percent to the current power level of 2,609 MWt.

The NRC staff did not identify any significant environmental impacts associated with the proposed action based on its evaluation of the information provided in the licensee's application and other available information. For further information with respect to the proposed action, see the licensee's application dated June 15, 2011 (ADAMS Accession No. ML112070659). The draft EA and draft FONSI are being published in the **Federal Register** with a 30-day public comment period ending February 15, 2013.

III. Draft Environmental Assessment

Plant Site and Environs

The CR–3 site is located in Citrus County, Florida on 4,738 acres (ac) (1,917 hectares (ha)), approximately 80 miles (mi) (129 kilometers [km]) north of Tampa, Florida. The plant is part of the larger Crystal River Energy Complex (CREC), which includes the single nuclear unit and four fossil-fueled units, Crystal River 1, 2, 4, and 5 (CR–1, CR–2, CR–4, and CR–5). CR–3 is adjacent to Crystal Bay, a shallow embankment of the Gulf of Mexico, and is midway between the mouths of two rivers: the Withlacoochee River, about 4.5 mi (7.2 km) to the north, and the Crystal River, about 2.5 mi (4 km) to the south. The Tampa-St. Petersburg-Clearwater metropolitan area is approximately 60 mi (96.5 km) south of Citrus County. CR–3 includes a pressurized light-water reactor (PWR) supplied by Babcock & Wilcox with a net electrical power output of 903 megawatts electric (MWe). FPC owns and operates CR–3. In this EA, the applicant is referred to as FPC or the licensee.

Crystal Bay, located in the Gulf of Mexico, is the source for cooling water for the main condensers at CR–3 and the other units at the CREC. CR–3 has a once-through heat dissipation system that circulates water through CR–3 in one of two modes of operation: open cycle (once-through cooling with no cooling towers in operation) and helper cycle (once-through cooling with mechanical draft cooling towers in operation). The CR–3 cooling water system consists of the intake canal, intake structures and pumps, circulating water intake piping, condensers, circulating water discharge piping, outfall structure, discharge canal, and cooling towers. CR–1 and CR–2 share the intake canal, discharge canal, and cooling towers with CR–3. CR–4 and CR–5 also share the discharge canal, which is lined with four permanent helper cooling towers. These helper cooling towers are operated during warmer months to allow CR–1, CR–2, and CR–3 to meet their combined National Pollutant Discharge Elimination System (NPDES) discharge limit of 96.5 degrees Fahrenheit (°F) (35.8 degrees Celsius (°C)) (Permit No. FL0000159). The licensee also regulates discharge temperatures by reducing power at CR–1 and CR–2, if necessary. To avoid having to rely on this rate-reduction method, in 2006, the licensee installed 67 State-approved additional temporary modular cooling towers for use as needed.

The intake canal, which extends into the Gulf of Mexico, is 14 mi (22.5 km) long. Current velocities at the mouth of the intake canal range from 0.6 to 2.6 feet per second (ft/s) (0.2 to 0.8 meters per second [m/s]). CR–3 withdraws cooling water from the Gulf of Mexico through its cooling water intake structure, located near the eastern end of the intake canal. Water from the Gulf is drawn into the intake canal and to the four intake pumps that circulate the non-contact cooling water through the plant. Water passes through eight external trash racks made of 3.6-in (9.2-cm) spaced vertical bars and seven 0.38-in (1-cm) mesh size traveling screens where it is pumped to a circulating-water system and an auxiliary cooling water system. The CR–3 system has a design intake volume of 680,000 gpm [gallons per minute] (42,840 L/s), with a combined condenser flow limit for all three units (CR–1, CR–2 and CR–3) of 1,897.9 million gallons per day (gpd) (4.9 million liters per minute [L/min]) from May 1 to October 31, and 1,120,000 gpd (2,912 L/min) from November 1 to April 30.

The heated water from the cooling water systems flows to a discharge canal shared with CR–1 and CR–2, and then back to Crystal Bay. The discharge canal extends west about 1.6 mi (2.6 km) to the point of discharge in Crystal Bay, and extends an additional 1.2 mi (1.9 km) beyond the discharge point. This discharge canal is the source of cooling system makeup water for CR–4 and CR–5. When CR–1, CR–2, and CR–3 are operating at maximum pumping capacity, the velocity in the discharge canal is about 2.4 ft/s (0.7 m/s) at low tide.

Background Information on the Proposed Action

By application dated June 15, 2011 (ADAMS Accession No. ML112070659), the licensee requested an amendment for an extended power uprate (EPU) for CR–3 to increase the licensed thermal power level from 2,609 MWt to 3,014 MWt for CR–3, which represents an increase of 15.52 percent above the current licensed thermal power. This change requires NRC approval prior to the licensee operating at that higher power level. The proposed action is considered an EPU by the NRC because it exceeds the typical 7-percent power increase that can be accommodated with only minor plant changes. An EPU typically involves extensive modifications to the nuclear steam supply system contained within the plant buildings.

The planned physical modifications to the plant needed in order to implement the proposed EPU would take place inside of existing buildings and previously-disturbed areas on the CR–3 site. The modifications were scheduled to be implemented over the course of two refueling outages, the first of which was completed in 2009, with the second phase scheduled for 2013. The 2009 outage produced a small increase in electrical output with no change in rated thermal power. The 2013 outage would increase the reactor thermal power and increase the electrical output to 168 MWe, however, the concrete containment at CR–3 delaminated in October 2009 during activities to create an opening in the containment for steam generator replacement. After replacing steam generators during 2009 outage, the licensee encountered additional containment delaminations during containment repair activities. The licensee is still in the process of determining further actions, and the plant is still in an outage. As a result, NRC suspended the review of the license renewal application temporarily (ADAMS Accession No. ML11112A122) until the licensee provides a concrete plan to repair the containment to original condition or better.

Approximately 760 people are currently employed at CR–3 on a full-time basis. For the recently completed 2009 outage, this workforce was augmented by an additional 1,000 EPU and steam generator replacement workers on average, with a peak of 1,800 workers. For the scheduled 2013 EPU-upgrade outage, the licensee estimates an average of 1,350 EPU-related construction workers on site. The increase of workers would be comparable to the number of workers required for a routine outage (typically 1,300 workers) and the peak construction workforce would be smaller than the FPC-reported peak workforce for the 2009 outage, which involved the replacement of major components, including the steam generators.

The Need for the Proposed Action

As stated in the licensee's application, the proposed action is to provide the licensee with the flexibility to increase the potential electrical output of CR–3. The proposed EPU will increase the output for CR–3 by about 405 MWt, from about 2,609 MWt to about 3,014 MWt.

Environmental Impacts of the Proposed Action

As part of the original licensing process for CR–3, the U.S. Atomic Energy Commission published a Final Environmental Statement (FES) in 1973 (ADAMS Accession No. ML091520178). The FES contains an evaluation of the potential environmental impacts associated with the operation of CR–3 over its licensed lifetime. In May 2011, the NRC published a draft supplemental environmental Impact Statement (SEIS) for CR–3 (ADAMS Accession No. ML11139A153). The 2011 draft SEIS evaluated the environmental impacts of operating CR–3 for an additional 20 years beyond its then-current operating license, extending the operation life until 2036. The NRC determined that the overall environmental impacts of license renewal were small. This NRC evaluation is presented in NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 44, Regarding Crystal River Unit 3 Nuclear Generating Plant (Draft Report for Comment)'' (draft SEIS–44). The NRC used information from FPC's license amendment request for the EPU, consultation with National Marine Fisheries Service (NMFS), the FES, and SEIS–44 to prepare the EA for the proposed EPU.

The licensee's application states that it would implement the proposed EPU without extensive changes to buildings or to other plant areas outside of buildings. Plant modifications required to implement the EPU would occur in two phases. Phase One was completed during a steam generator replacement refueling outage in the fall of 2009. Plant modifications made during this first phase were intended to make the secondary side of the plant more efficient. Phase Two, which is scheduled for the spring of 2013, would include the necessary hardware changes to accommodate the higher operating temperatures of the EPU. Plant modifications to accommodate a power increase include CR–3 switching to a more highly enriched uranium fuel, an operational change in reactor thermal-hydraulic parameters, and upgrade of the Balance of Plant capacity by component replacement or modifications. With the exception of the high-pressure turbine rotor replacement, the required plant modifications would be generally small in scope. Other plant modifications include replacing selected feedwater heaters; providing additional cooling for some plant systems; upgrading various electrical equipment/components to accommodate higher currents; accommodating greater steam and condensate flow rates; and upgrading instrumentation to include minor items such as replacing parts, changing set points, and modifying software.

Increasing the plant's rated thermal power to 168 MWe would also increase the amount of steam generated and the temperature of the circulating water. In order for the licensee to comply with the plant's NPDES thermal limits, two mitigation options are currently being considered: a newly constructed helper cooling tower, or seasonal load reduction. If the first option were selected, a new mechanical-draft cooling tower would be installed on a previously disturbed site, currently occupied by the CREC percolation clarifier pond and south of the existing helper cooling towers. The cooling tower would operate as a once-through cooling tower and, if selected, the licensee would need to apply to the Florida Department of Environmental Protection (FDEP) for a modification of their current NPDES permit. FDEP would determine the actual operating procedures, discharge locations, and timeframes of the new cooling tower option during this permit modification process. Under the second option of seasonal load reduction management, the licensee would manage the discharge canal water through the operation of the existing cooling towers. This strategy has been used at CREC (particularly for CR–1 and CR–2, the fossil fuel units) in the past when the existing cooling towers have been insufficient in meeting NPDES discharge limits due to climatic factors. Under EPU conditions, the licensee anticipates that using this option would require the existing helper cooling towers to operate more frequently and over a longer seasonal period. The potential environmental impacts of both

of these cooling options are evaluated and discussed in this assessment.

The sections below describe the potential nonradiological and radiological impacts to the environment that could result from the proposed EPU.

Nonradiological Impacts

Land Use and Aesthetic Impacts

Potential land use and aesthetic impacts from the proposed EPU include impacts from proposed plant modifications at CR–3. While the licensee proposes some plant modifications, all plant changes related to the proposed EPU would occur within existing structures, or within previously disturbed areas on the CREC site. In the 1960s, the developed area of the CREC site underwent clearing, filling, and grading during this original construction, including being covered with a three to five foot layer of fill. Consequently, there are no undisturbed land areas within the developed CREC site. During the 2009 steam generator replacement outage, a 1 ac (0.4 ha), previously disturbed area was converted into a permanent operational material and equipment lay-down area. An additional 3.5 ac (1.4 ha) was converted to overflow parking, and will likely be used as overflow parking again for the 2013 outage.

If the licensee decides to construct a helper-cooling tower, the new mechanical draft-cooling tower would be located on a small previously disturbed parcel of land near the CREC percolation clarifier pond. The construction and operation of the proposed 73.5 ft (22.4 m), 289 ft (88.1 m) diameter cooling tower would affect approximately 5 ac (2 ha), some of which would be temporarily used as a construction lay-down area.

If the load reduction management option were chosen, no land use changes would occur.

Other than the activities described above, no new construction would occur outside of the developed area of the CREC site, and no expansion of existing buildings, roads, parking lots, or storage areas are required to support the proposed EPU. Existing parking lots, road access, equipment lay-down areas, offices, workshops, warehouses, and restrooms would be used during plant modifications. In addition, there are no planned modifications to transmission lines. Because land use conditions would not change, and because any land disturbance has and would occur within previously disturbed areas, there would be no significant land use or aesthetic impacts from EPU-related plant modifications at CR–3.

Air Quality Impacts

CR–3 is located within the West Florida Intrastate Air Quality Control Region (AQCR). All of Florida, including the West Florida Interstate AQCR, are designated as being in attainment or unclassifiable for all criteria pollutants in the U.S. Environmental Protection Agency's (EPA) regulations at 40 CFR 81.310. Orange County, Duval County, the Tampa Bay area including Hillsborough and Pinellas Counties, and Southeast Florida including Dade, Broward, and Palm Beach Counties continue to be classified by the FDEP as attainment/maintenance areas for ozone and Tampa is a maintenance area for lead. The closest non-attainment area to CR–3 is 275 mi (442.5 km) north in Bibb County, Georgia. The entire State remains unclassifiable for particulate matter, 10 microns or less in diameter (PM_{10}), based on the EPA not yet considering this pollutant for attainment determinations. Unclassifiable areas are usually treated as attainment areas. The nearest designated mandatory Class 1 Federal area, the Chassahowitzka National Wildlife Refuge, is 13 mi (20.9 km) south of CR–3.

The CREC qualifies as a major source under the FDEP Title V permit program by virtue of the operation of the coal-fired units on contiguous parcels all under the control of FPC and, therefore, is required to obtain a Title V permit (Permit No. 0170004–004–AV). Although none of the permit stipulations pertain directly to the operation of CR–3, the existence of that permit nevertheless has an indirect impact on the operation, monitoring, and recordkeeping requirements for stationary sources of criteria pollutants affiliated with CR–3. Specifically, drift from an auxiliary cooling tower shared between CR–3 and two coal-fired units is addressed in the permit, and three diesel-fueled emergency power generators affiliated exclusively with the nuclear reactor are identified as unregulated stationary sources. NRC expects no changes to the emissions from these sources as a result of the EPU.

During EPU implementation, some minor and short duration air quality impacts would occur from other non-regulated sources. Vehicles of the additional outage workers needed for EPU implementation would generate the majority of air emissions during the proposed EPU-related modifications. However, this source will be short term and temporary. If the new helper cooling tower option were selected, the effects of additional workers and associated vehicles during the 18-month construction period would be similarly short term and temporary. In addition, the majority of the EPU activities would be performed inside existing buildings and would not cause additional atmospheric emissions.

If the new helper cooling tower option were selected, a new cooling tower onsite would result in added particulate matter (PM) emissions. FDEP regulations limit PM emissions to 25 tons per year, and PM_{10} emissions to 15 tons per year. Potential PM and PM_{10} emissions from the new cooling tower were evaluated by the licensee in 2007 and the cooling tower design was subsequently modified to meet PM emission thresholds by reducing the flow rate through the tower. The predicted emissions from the modified design are 91.2 tons PM per year and 5.5 tons PM_{10} per year. PM emissions from the cooling tower would be confined to the CREC property, with minimal visibility impacts.

Therefore, the NRC staff expects no significant impacts to regional air quality from the proposed EPU beyond those air impacts evaluated for draft SEIS–44, including potential minor and temporary impacts from worker activity and impacts from a possible new cooling tower.

Water Use Impacts

Groundwater

Groundwater at the CREC is drawn from the Floridian aquifer system, which is a thick, vertically continuous sequence of Tertiary-age carbonate rocks (limestone and dolomite) with high relative permeability and regional extent. Although the CREC currently maintains 14 onsite production wells completed in the Upper Floridian aquifer, CR–3 draws its water only from the south treatment plant, which is supplied by three wells. Groundwater is used at CR–3 for boilers and steam generators, ash processes, fire protection, and drinking water. CR–3 currently uses approximately 0.73 million gallons per day (gpd) (2.8 million liters (L) per day) of freshwater per day, which is well below the 2 million gpd (7.6 liters per day) authorized by the Southwest Florida Water Management District water use permit (Permit No. 20004695.004). This amount represents approximately three percent of the total groundwater consumed in Citrus County. The facility's individual wastewater facility permit administrated by the FDEP regulates the percolation ponds onsite

and specifies the site's groundwater monitoring requirements.

Under the EPU, the licensee does not expect to significantly change the amount of freshwater use or supply source. With an expected increase of 1,350 workers supporting 2013 EPU construction activities, NRC expects potable water use to increase during the outage and return back to the regular operating levels after EPU implementation. It is unlikely this potential increase in temporary groundwater use during the EPU construction activities would have any effect on other local and regional groundwater users. This was demonstrated during the 2009 outage, which had a larger increase of onsite workers (a peak of 1,800) and caused no public water supply shortages. Based on the 2009 outage, the NRC staff expects no significant impact on groundwater resources during proposed EPU construction activities or following EPU implementation.

Surface Water

FDEP regulates the Florida Surface Water Quality Standards through a National Pollutant Discharge Elimination System (NPDES) permit, which also establishes the maximum area subject to temperature increase (mixing zone), maximum discharge temperatures, and chemical monitoring requirements. CR–1, CR–2, and CR–3 are currently operating under NPDES Permit No. FL0000159. CR–4 and CR–5 operate under a separate NPDES permit. The intake structure for the CR–3 main condenser uses four circulating water pumps, which provide a total flow capacity of 680,000 gpm (42,840 L/s). Two of the pumps are rated at 167,000 gpm (10,521 L/s) and two are rated at 179,000 gpm (11,277 L/s). Service pumps withdraw an additional 10,000 to 20,000 gpm (630 to 1,260 L/s), depending on system demand. The NPDES permit limits the combined flow for CR–1, CR–2, and CR–3 to 1,898 million gpd (4.9 million liters per minute [L/min]) from May 1 to October 31, and 1,613 million gpd (4.2 million L/min) from November 1 to April 30.

Cooling water for all CREC units is discharged back to the Gulf through a common discharge canal, located north of CR–1, CR–2, and CR–3. The site discharge canal extends about 1.6 mi (2.6 km) west into the Gulf to the point of discharge in Crystal Bay, and then another 1.2 mi (1.9 km) beyond the discharge point. The helper cooling towers withdraw water from the discharge canal when needed to comply with the NDPES thermal discharge limit of 96.5 °F (35.8 °C).

The NPDES permit stipulates that prior to the use of any biocide or chemical additive used in the cooling system or any other portion of the treatment system, a permit revision from the FDEP is required. As regulated by the current CR–3 NPDES permit, the plant periodically adds chlorine in regulated quantities to control biofouling organisms. Because FDEP regulates discharges and requires chemical monitoring, NRC expects that the authorized discharges will not exceed the NPDES permit maximum total residual oxidant (chlorine) concentration at the unit outfall of 0.01 milligrams per unit (mg/L) after EPU implementation.

To accommodate the increase in thermal output as a result of the EPU, the licensee has defined two cooling options: A new helper cooling tower, or load reduction management. The helper cooling tower option would utilize a mechanical draft cooling tower designed to operate in a once-through mode, discharging either to the intake or discharge canal, as is necessary. If this option is selected by the licensee, some of the current modular cooling towers could be discontinued. The new cooling tower would not require the use of any chemicals or biocides to control biofouling organisms and would not significantly increase total dissolved solids concentrations in the cooling water discharge. The actual operational procedures of the new cooling tower would be defined during the NPDES permit modification process, which would be required and administered by FDEP. If the load reduction management option were selected, the temporary modular towers, as well as CREC's permanent cooling towers, would continue to operate. Discharge canal temperatures would be moderated by reducing power at either CR–1 or CR–2 in order to comply with the site's NPDES permit. This second option would also likely extend the length of time per season that the current cooling towers are used.

As part of the proposed EPU, the licensee consulted with the Florida Department of Community Affairs for a review of coastal zone consistency. Currently, FDEP has the authority to review all Federal licenses for coastal zone consistency with Section 307 of the Coastal Zone Management Act. For CR–3, CR–4, and CR–5, the coastal zone consistency certification is documented by the FDEP in Section XXV, ''Coastal Zone Consistency,'' of the licensee's Conditions of Certification, updated most recently on August 1, 2012.

Aquatic Resource Impacts

The potential impacts to aquatic resources from the proposed action could include impingement of aquatic life on barrier nets, trash racks, and traveling screens; entrainment of aquatic life through the cooling water intake structures and into the cooling water systems; and effects from the discharge of chemicals and heated water.

Because the proposed EPU will not result in an increase in the amount or velocity of water being withdrawn from or discharged to the Gulf of Mexico, NRC expects no increase in aquatic impacts from impingement and entrainment beyond the current impact levels. Currently, all organisms impinged on the trash racks and traveling screens would be killed, as would most, if not all, entrained organisms. If the licensee selects the cooling tower option, a portion of the discharge would be routed to the site intake canal in late fall and winter, which would reduce the amount of withdrawal from the Gulf of Mexico. Reducing the amount of water withdrawal could reduce entrainment effects during cooler months. Under either cooling option, the licensee would continue its mitigation and monitoring program, developed in conjunction with NMFS, for the capture release and protection of sea turtles that enter the intake canal.

Regardless of which cooling option (helper cooling tower or load reduction management) is chosen, FPC will comply with its NPDES discharge limit of 96.5 °F (35.8 °C). If the cooling tower option is selected, the mechanical draft cooling tower would be constructed to accommodate the increase in thermal loads, as well as allowing the licensee to retire a portion of its 67 temporary modular towers. If the load reduction management option were selected, the temporary towers as well as CREC's permanent cooling towers would continue to operate. Discharge canal temperatures would be moderated by reducing power at either CR–1 or CR–2 in order to comply with the site's NPDES permit. This second option would extend the length of time per season that the current cooling towers are used, as necessary. Because NRC expects the surface water, temperature not to exceed 96.5 °F (35.8 °C), as a result of the proposed EPU, the NRC staff concludes that there are no significant impacts to aquatic biota from the proposed EPU.

Essential Fish Habitat Consultation

The Magnuson-Stevens Fishery Conservation and Management Act

(MSA) identifies the importance of habitat protection to healthy fisheries. Essential Fish Habitat (EFH) is defined as those waters and substrata necessary for spawning, breeding, feeding, or growth to maturity (Magnuson-Stevens Act, 16 USC 1801 *et seq.*). Designating EFH is an essential component in the development of Fishery Management Plans to minimize habitat loss or degradation of fishery stocks and to take actions to mitigate such damage. The consultation requirements of Section 305(b) of the MSA provide that Federal agencies consult with the Secretary of Commerce on all actions or proposed actions authorized, funded, or undertaken by the agency that may adversely affect EFH. On June 1, 2011, an EFH assessment for the proposed operating license renewal was sent to the NMFS under separate cover to initiate an EFH consultation (ADAMS Accession No. ML11140A100). The EFH assessment for license renewal also discussed the proposed EPU and the potential new cooling tower option. The submitted EFH assessment found that continued operation of CR–3 would have no adverse effects to EFH for two of the species of concern (*Seriola dumerili* and *Epinephelus adscensionis*) and minimal adverse effects for the remaining 17 species. The EFH assessment for license renewal discussed the proposed EPU conditions, stating that the effects of impingement, entrainment, and the thermal plume would not be increased by the EPU due to the fact that flow rates will not be increased from current operating levels, and any increase in thermal output will be mitigated, potentially by an additional cooling tower. Therefore, the EFH issued for license renewal is also valid for NRC's requirements under Section 7 of the Endangered Species Act (ESA) for the proposed EPU.

NMFS responded to NRC's EFH assessment on July 25, 2011 (ADAMS Accession No. ML11216A130). In their letter, NMFS stated that the agency currently had insufficient staffing resources to review the draft SEIS, and that it should be noted that NMFS position is neither supportive of, nor in opposition to, the proposed relicensing activities. This letter fulfilled the NRC's requirements under Section 7 of the ESA with notification to NMFS.

The following table identifies the species that the NRC considered in its EFH assessment.

TABLE 1—SPECIES OF FISH ANALYZED IN EFH ASSESSMENT

Fishery management plan	Scientific name	Common name
Red Drum	*Sciaenops ocellatus*	red drum.
Reef Fish	*Mycteroperca bonaci*	black grouper.
	Lutjanus jocu	dog snapper.
	Diplectrum bivittatum	dwarf sand perch.
	Mycteroperca microlepis	gag grouper.
	Lutjanus griseus	gray snapper.
	Seriola dumerili	greater amberjack.
	Lachnolaimus maximus	hogfish.
	Lutjanus synagris	lane snapper.
	Epinephelus striatus	Nassau grouper.
	Epinephelus morio	red grouper.
	Epinephelus adscensionis	rock hind.
	Lutjanus apodus	schoolmaster.
	Rhomboplites aurorubens	vermilion snapper.
	Ocyurus chrysurus	yellowtail snapper.
Coastal Migratory Pelagics	*Scomberomorus maculatus*	Spanish mackerel.
Shrimp	*Farfantepenaeus duorarum*	pink shrimp.
	Litopenaeus setiferus	white shrimp.
Stone Crabs	*Menippe mercenaria*	Florida stone crab.

Terrestrial Resources Impacts

CR–3 uses approximately 27 ac (11 ha) of previously disturbed land within the 1,062 ac (430 ha) developed portion of the 4,738 ac (1,917 ha) CREC. The remainder of the CREC site has been left undeveloped, providing a buffer zone containing 3,676 ac (1,488 ha) of primarily hardwood hammock forest and pineland, salt marshes, small tidal creeks, and freshwater swamps, protected against encroachment from any other coastal development. As previously discussed, there remain no undisturbed areas and no native solids or vegetation communities within the developed CREC site. Within the disturbed facility areas, small strips of vegetation occur on roadsides, and open lawn areas are dominated by grasses. After September 11, 2001, a 0.9 ac (0.4 ha), which was previously mixed-hardwood wetland, was altered for security reasons. All trees in this area were cut to accommodate construction of new security facilities. This area was later converted into a permanent lay-down area during the 2009 steam generator replacement outage. An additional 3.5 ac (1.4 ha) grass area was converted to overflow parking, and will likely be used as overflow parking again for the 2013 outage.

If the helper cooling tower option is chosen, the new mechanical draft cooling tower would be constructed on a small parcel of land which was formally salt marsh, but was filled in 1970 by the site's previous owners. This area, approximately 3,600 ft (1,097 m) west of CR–3 was also the site of the former CR–3 meteorological towers (which is now relocated) and is currently occupied by the CREC percolation clarifier pond. The proposed 73.5 ft (22.4 m) cooling tower would have a diameter of 289 ft (88.1 m) and would require approximately 18 months to build. The previously disturbed areas affected by construction of the new tower would total approximately 5 ac (2 ha), some of which would be converted to an additional construction lay-down area.

Because the new cooling tower option would only impact previously disturbed areas onsite, impacts that could potentially affect terrestrial resources would include disturbance or loss of habitat, construction and EPU-related noise and lighting, and sediment transport or erosion during the 2013 outage and the 18-month construction period for the new cooling tower. Noise and lighting would not adversely affect terrestrial species beyond effects experienced during previous outages because EPU-related construction modification activities would take place

during outage periods, which are typically periods of heightened activity. Noise and lighting impacts from the possible construction of a new cooling tower would only affect terrestrial species temporarily during the construction period. If the load reduction management option is selected, there would be no construction-related impacts to terrestrial species beyond those related to the 2013 outage. Also, during the 2009 outage, prior to the grading or grubbing conducted for the lay-down areas, the licensee performed a survey of the areas in accordance with the licensee's conditions of site certification under FDEP and followed best management practices to ensure that any ecological resources were protected. No changes to transmission lines or right of way (ROW) maintenance practices are required for the EPU. Thus, NRC expects no significant impacts on terrestrial resources associated with the proposed EPU.

Threatened and Endangered Species Impacts

Under Section 7 of the Endangered Species Act of 1973, as amended (ESA), Federal agencies, in consultation with the U.S. Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (as appropriate), must ensure that actions the agency authorizes, funds, or carries out are not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat.

A number of species in Citrus County are listed as threatened or endangered under the ESA, and other species are designated as meriting special protection or consideration. These include birds, fish, aquatic and terrestrial mammals, flowering plants, insects, and reptiles that could occur on or near CR–3 facility areas and possibly along the electrical transmission line ROWs. The most common occurrences of threatened or endangered species observed within the CREC boundary are five species of sea turtles: loggerhead turtles (*Caretta caretta*), Atlantic green turtles (*Chelonia mydas*), Kemp's ridley turtles (*Lepidochelys kempii*), hawksbill turtles (*Eretmochelys imbricata*), and leatherback turtle (*Dermochelys coriacea*). FPC has a mitigation and monitoring program, developed in conjunction with NMFS, in place for the capture-release and protection of sea turtles that enter the intake canal. The Florida manatee (*Trichechus manatus latirostris*), a subspecies of the West Indian manatee (*Trichechus manatus*), also has been documented at CREC. Designated critical habitat for the Florida manatee is located in the Crystal River and its headwaters, adjacent to the southern boundary of the CREC. The NRC assessed potential impacts on the Florida manatee from operation of CR–3 in the draft SEIS–44. Three additional federally protected animals have been observed within the CREC site boundary, including American alligators (*Alligator mississippiensis*), wood storks (*Mycteria americana*), and bald eagles (*Haliaeetus leucocephalus*). No other critical habitat areas for endangered, threatened, or candidate species are located at the CREC site or along the transmission line ROWs.

The following table identifies the species found on or near the CREC site or the transmission line ROWs that the NRC assessed in draft SEIS–44.

TABLE 2—FEDERALLY LISTED SPECIES ASSESSED IN DRAFT SEIS–44

Scientific name	Common name	ESA status [a]
Birds:		
Aphelocoma coerulescens	Florida scrub-jay	T
Charadrius melodus	piping plover	T
Grus americana	whooping crane	E/XN
Haliaeetus leucocephalus	bald eagle	T
Mycteria americana	wood stork	E
Fish:		
Acipenser oxyrinchus desotoi	gulf sturgeon	T
Pristis pectinata	smalltooth sawfish	E
Marine Mammals:		
Trichechus manatus latirostris	Florida manatee	E/CH
Reptiles:		
Drymarchon corais couperi	eastern indigo snake	T
Sea Turtles:		
Caretta caretta	loggerhead turtle	T
Chelonia mydas	green turtle	E
Dermochelys coriacea	leatherback turtle	E
Eretmochelys imbricata	hawksbill turtle	E
Lepidochelys kempii	Kemp's ridley turtle	E
Crocodilians:		
Alligator mississippiensis	American alligator	T/SA
Plants:		
Bonamia grandiflora	Florida bonamia	T
Campanula robinsiae	Brooksville bellflower	E
Chrysopsis floridana	Florida golden aster	E
Dicerandra cornutissima	longspurred mint	E
Eriogonum longifolium var. *gnaphalifo-lium*	scrub buckwheat	T
Justicia cooleyi	Cooley's water willow	E
Nolina brittoniana	Britton's beargrass	E

[a] E = endangered; T = threatened; T/SA = threatened due to similarity of appearance; EXPN, XN = experimental, nonessential; CH = critical habitat.

Source: U.S. Fish and Wildlife Service.

NRC has consulted with NMFS since 1982 regarding sea turtle kills, captures, or incidental takes. A 2002 NMFS biological opinion concluded that operation of the CREC is not likely to jeopardize the continued existence of the five sea turtle species (ADAMS Accession No. ML022460361). The 2002 NMFS biological opinion provides for limited incidental takes of threatened or endangered sea turtles. Correspondence between the licensee, FWS, and NMFS in connection with the 2011 license renewal environmental review indicated that effects to endangered, threatened, or candidate species, including a variety of sea turtles and manatees, would not significantly change, as a result of issuing a license renewal for CR–3.

Because any increase in thermal output, as a result of the proposed EPU will be mitigated either by a new cooling tower option or load reduction management, the EPU will not increase thermal exposure to aquatic biota at the site. NRC expects the licensee capture-release and monitoring program for sea turtles and NRC interactions with NMFS regarding incidental takes to continue under the terms and conditions of the 2002 biological opinion. Therefore, NRC expects the proposed EPU would not change the effects of plant operation on threatened and endangered aquatic species.

Planned construction-related activities associated with the proposed EPU primarily involve changes to existing structures, systems, and components internal to existing buildings and would not involve earth disturbance, with the exception of the construction of the new helper cooling tower, if selected. Traffic and worker activity in the developed parts of the plant site during the 2013-outage modifications would be somewhat greater than a normal refueling outage. During the 18-month construction period of the new helper-cooling tower, impacts that could potentially affect terrestrial resources would include disturbance or loss of habitat, construction and EPU-related noise and lighting, and sediment transport or erosion. As described in the ''Terrestrial Resource Impacts'' section, any potential impacts from cooling tower construction would only affect terrestrial species temporarily during the construction period. Any ground disturbing activities would require the licensee to conduct a survey and follow best management practices to ensure that any ecological resources were protected. No changes to transmission lines or ROW maintenance practices are required for the EPU.

The NRC concluded in draft SEIS–44 that the continued operation of CR–3 was not likely to adversely affect terrestrial wildlife. In general, the effects of changes to the terrestrial wildlife habitat on the CR–3 site from the proposed EPU should not exceed those potential effects on terrestrial wildlife evaluated in draft SEIS–44, including potential minor and temporary impacts from EPU-related worker activity and any impacts from the construction of a new mechanical draft-cooling tower. Implementing the EPU would not change water withdrawal or discharge rates or effluent temperatures outside of those in the present NPDES permit. Due to the lack of such changes, the NRC staff concludes that the incremental effect of the EPU would have no additional effect on endangered aquatic species beyond those already addressed in the 1998 biological assessment and NMFS 2002 biological opinion (ADAMS Accession Nos. ML12009A034 and ML022460361, respectively).

Historic and Archaeological Resources Impacts

A 1973 archaeological survey (conducted on the recommendation of the Florida Division of Historical Resources) identified 20 archaeological sites within the CREC property boundaries, consisting of 18 prehistoric sites, one prehistoric site with historic components, and one of unspecified affiliation. Records at the Florida Master Site File in the Florida Division of Historical Resources confirm that these are the only recorded archaeological sites within CREC. These sites have not been evaluated for listing on the National Register for Historic Places (NRHP) and they remain potentially eligible until a formal evaluation is conducted. In addition, there are 63 recorded archaeological sites along the transmission line ROWs. Most of these archaeological sites have been determined ineligible for listing on NRHP, but nine have not been formally evaluated.

As previously discussed, all plant modifications related to the proposed EPU would occur within existing structures, or within previously disturbed areas on the CREC site. The developed area of the CREC site underwent clearing, filling, and grading during power plant construction, including being covered with a three to five foot layer of fill. Consequently, no areas remain undisturbed within the developed portions of the CREC site. Any potential ground disturbances would occur within this area. The licensee also has corporate procedures for the protection of archaeological resources, including consultation with the Florida State Historic Preservation Office, in place that apply to any ground disturbing activities within the CREC and along transmission lines. The 2009 EPU and steam generator replacement-outage did not adversely impact any archaeological sites on historic properties in the vicinity of CR–3, because all of the outage activity took place away from known archaeological sites within the previously disturbed developed portions of the plant site. Because no ground disturbance or EPU-related construction activities would occur outside of previously disturbed areas, there would be no significant impact from the proposed EPU-related modifications on historic and archaeological resources at the CREC site.

Socioeconomic Impacts

Potential socioeconomic impacts from the proposed EPU include increased demand for short-term housing, public services, and increased traffic in the region due to the temporary increase in the size of the workforce at CR–3 required to implement the EPU. The proposed EPU also could generate increased tax revenues for the State and surrounding counties due to increased power generation.

Approximately 760 full-time employees work at CR–3. For the recently completed 2009 outage, this workforce was augmented by an additional peak of 1,800 workers. For the upcoming 2013 outage, the licensee estimates a peak of 1,350 EPU-related workers, which is only slightly higher than a typical outage peak of 1,300 workers. Once EPU-related plant modifications have been completed, the size of the refueling outage workforce at CR–3 would return to normal levels and would remain similar to pre-EPU levels, with no significant increases during future refueling outages. The size of the regular plant operations workforce would be unaffected by the proposed EPU.

Based on the 2009 outage, NRC expects most of the EPU plant modification workers to relocate temporarily to the Tampa-St. Petersburg-Clearwater metropolitan area during the upcoming 2013 outage, resulting in short-term increased demands for public services and housing. Because plant modification work would be temporary, most workers would stay in available rental homes, apartments, mobile homes, and camper-trailers.

There were no housing or public services shortages during the 2009 outage, which employed a significantly

larger number of workers than is expected during the upcoming 2013 outage. Therefore, the increase in plant employment during the 2013 outage would have little or no noticeable effect on the availability of housing in the region.

The additional number of refueling outage workers and truck material and equipment deliveries needed to support EPU-related plant modifications could cause short-term level of service impacts (restricted traffic flow and higher incident rates) on secondary roads in the immediate vicinity of CR–3. The licensee expects increased traffic volumes during the upcoming 2013 refueling outage. However, based on a 2007-traffic study commissioned by the licensee, and the results of the 2009 refueling outage (which the study showed had a greater potential for impact to transportation in the region than the 2013 outage), only small traffic delays are anticipated during the 2013 outage. For the 2009 outage, the licensee successfully established a temporary offsite parking area, using shuttle buses to transport workers on and off the site to mitigate congestion at the intersection of US–19/US–98 and West Power Line Road. Because fewer workers will be required for the 2013 outage, offsite parking may not be used, however, the licensee recognizes that a similar approach to the 2009 outage could be utilized, if necessary.

CR–3 currently pays annual real estate property taxes to Citrus County, the Board of County Commissioners, the Citrus County School District, the Southwest Florida Water Management District, the Citrus County Hospital Board, the Homosassa Special Water District, mosquito control, and the county's municipalities to fund their respective operating budgets. The annual amount of future property taxes CR–3 would pay could take into account the increased value of CR–3, as a result of the EPU and increased power generation.

Due to the short duration of EPU-related plant modification activities, there would be little or no noticeable effect on tax revenues generated by additional temporary workers residing in Citrus County. In addition, there would be little or no noticeable increased demand for housing and public services or level-of-service traffic impacts beyond what is experienced during normal refueling outages at CR–3. Therefore, there would be no significant socioeconomic impacts from EPU-related plant modifications and power plant operations under EPU conditions in the vicinity of CR–3.

Environmental Justice Impact Analysis

The environmental justice impact analysis evaluates the potential for disproportionately high and adverse human health and environmental effects on minority and low-income populations that could result from activities associated with the proposed EPU at CR–3. Such effects may include human health, biological, cultural, economic, or social impacts. Minority and low-income populations are subsets of the general public residing in the vicinity of CR–3, and all are exposed to the same health and environmental effects generated from activities at CR–3.

NRC considered the demographic composition of the area within a 50 mi (80.5 km) radius of CR–3 to determine the location of minority and low-income populations using the U.S. Census Bureau data for 2010 and whether they may be affected by the proposed EPU.

According to 2010 census data, an estimated 1,039,919 people live within a 50 mi (80.5 km) radius of CR–3. Minority populations within 50 mi (80.5 km) comprise 20 percent (approximately 207,470 persons). The largest minority group was Hispanic or Latino (of any race) (approximately 92,015 persons or 9 percent), followed by Black or African American (approximately 80,979 persons or 8 percent). The 2010 census block groups containing minority populations were concentrated primarily east of CR–3. Minority populations within Citrus County comprise 10.6 percent of the total population, with the largest minority groups being Hispanic or Latino (of any race) with 4.7 percent, followed by Black or African American with 3 percent.

According to the 2010 American Community Survey 1-Year Estimates data, 17.3 percent of the total population and 12.3 percent of families residing in Citrus County were considered low-income, living below the 2010 federal poverty threshold. The 2010 federal poverty threshold was $11,139 for an individual and of $22,314 for a family of four. According to the 2010 American Community Survey 1-Year census estimates, the median household income for Florida was $53,093, while 12.0 percent of families and 16.5 percent of the state population were determined to be living below the Federal poverty threshold. Citrus County had a lower median household income average ($43,791) and slightly higher percentages of families and individuals living below the poverty threshold, respectively.

Potential impacts to minority and low-income populations would mostly consist of environmental and socioeconomic effects (e.g., noise, dust, traffic, employment, and housing impacts). Radiation doses from plant operations after implementation of the EPU are expected to continue to remain well below regulatory limits.

Noise and dust impacts would be temporary and limited to onsite activities. Minority and low-income populations residing along site access roads could experience increased commuter vehicle traffic during shift changes. Increased demand for inexpensive rental housing during the EPU-related plant modifications could disproportionately affect low-income populations; however, due to the short duration of the EPU-related work and the availability of housing, impacts to minority and low-income populations would be of short duration and limited. According to the 2010 census information, there were approximately 14,722 vacant housing units in Citrus County.

Based on this information and the analysis of human health and environmental impacts presented in this EA, the proposed EPU would not have disproportionately high and adverse human health and environmental effects on minority and low-income populations residing in the vicinity of CR–3.

Nonradiological Cumulative Impacts

The NRC considered potential cumulative impacts on the environment resulting from the incremental impact of the proposed EPU when added to other past, present, and reasonably foreseeable future actions in the vicinity of CR–3. For the purposes of this analysis, past actions are related to the construction and licensing of CR–3, present actions are related to current operations, and future actions are those that are reasonably foreseeable through the end of station operations, including operations after implementation of the EPU.

The NRC concluded that there would be no significant cumulative impacts to air quality, groundwater, threatened and endangered species, or historical and archaeological resources near CR–3 because the contributory effect of ongoing actions within the region are regulated and monitored through a permitting process (e.g., NPDES and 401/404 permits under the Clean Water Act) under State or Federal authority. In these cases, impacts are managed as long as these actions comply with their respective permits and conditions of certification.

Surface water and aquatic resources were examined for potential cumulative impacts. For both resource areas, the geographic boundary for potential cumulative impacts is the area of the post-EPU thermal mixing zone. If the proposed EPU is approved and is implemented, CR–3's mixing zone will not change from pre-uprate conditions during full flow and capacity because any increase in thermal discharge temperature will be mitigated either by a new cooling tower option or by load reduction management. The NRC anticipates that CR–3 will continue to operate post-EPU in full compliance with the requirements of the FDEP NPDES permit. FDEP would evaluate the licensee's compliance with the NPDES permit and take action, as required, to ensure compliance.

Cumulative socioeconomic impacts from the proposed EPU and continued operation of CR–3 would occur during the spring 2013 refueling outage. The increased demand for temporary housing, public services, and increased traffic from the EPU-related outage workforce would have a temporary cumulative additive effect on socioeconomic conditions in local communities. However, these cumulative effects would be similar to those experienced during normal refueling outages at CR–3 caused by current operations.

Nonradiological Impacts Summary

As discussed above, the proposed EPU would not result in any significant nonradiological impacts. Table 3 summarizes the nonradiological environmental impacts of the proposed EPU at CR–3.

TABLE 3—SUMMARY OF NONRADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use	No significant impacts on land use conditions and aesthetic resources in the vicinity of CR–3.
Air Quality	No significant impacts to air quality from temporary air quality impacts from vehicle emissions related to EPU construction workforce.
Water Use	No significant changes to impacts caused by current operations. No significant impacts on groundwater or surface water resources.
Aquatic Resources	No significant changes to impacts caused by current operation due to impingement, entrainment, and thermal discharges.
Terrestrial Resources	No significant impacts to terrestrial resources.
Threatened and Endangered Species	No significant changes to impacts caused by current operations.
Historic and Archaeological Resources	No significant impacts to historic and archaeological resources onsite or in the vicinity of CR–3.
Socioeconomics	No significant socioeconomic impacts from EPU-related temporary increase in workforce.
Environmental Justice	No disproportionately high or adverse human health and environmental effects on minority and low-income populations in the vicinity of CR–3.
Cumulative Impacts	No significant changes to impacts caused by current operations.

Radiological Impacts

Radioactive Gaseous and Liquid Effluents and Solid Waste

CR–3 uses waste treatment systems to collect, process, recycle, and dispose of gaseous, liquid, and solid wastes that contain radioactive material in a safe and controlled manner within NRC and EPA radiation safety standards. The licensee's evaluation of plant operation under proposed EPU conditions predict that no physical changes would be needed to the radioactive gaseous, liquid, or solid waste systems.

Radioactive Gaseous Effluents

The gaseous waste management systems include the radioactive gaseous system, which manages radioactive gases generated during the nuclear fission process. Radioactive gaseous wastes are principally activation gases and fission product radioactive noble gases resulting from process operations, including continuous cleanup of the reactor coolant system, gases used for tank cover gas, and gases collected during venting. The licensee's evaluation determined that implementation of the proposed EPU would not significantly increase the inventory of carrier gases normally processed in the gaseous waste management system, because plant system functions are not changing, and the volume inputs remain the same. The licensee's analysis also showed that the proposed EPU would result in an increase (a bounding maximum of 15.5 percent for all noble gases, particulates, radioiodines, and tritium) in the equilibrium radioactivity in the reactor coolant, which in turn increases the radioactivity in the waste disposal systems and radioactive gases released from the plant.

The licensee's evaluation concluded that the proposed EPU would not change the radioactive gaseous waste system's design function and reliability to safely control and process the waste. The existing equipment and plant procedures that control radioactive releases to the environment will continue to be used to maintain radioactive gaseous releases within the dose limits of 10 CFR 20.1302 and the as low as is reasonably achievable (ALARA) dose objectives in 10 CFR Part 50, Appendix I.

Radioactive Liquid Effluents

The liquid waste management system collects, processes, and prepares radioactive liquid waste for disposal. Radioactive liquid wastes include liquids from various equipment drains, floor drains, the chemical and volume control system, steam generator blowdown, chemistry laboratory drains, laundry drains, decontamination area drains, and liquids used to transfer solid radioactive waste. The licensee's evaluation shows that the proposed EPU implementation would not significantly increase the inventory of liquid normally processed by the liquid waste management system. This is because the system functions are not changing and the volume inputs remain the same. The proposed EPU would result in an increase in the equilibrium radioactivity in the reactor coolant (15.5 percent), which in turn would impact the concentrations of radioactive nuclides in the waste disposal systems.

Because the composition of the radioactive material in the waste and the volume of radioactive material processed through the system are not expected to significantly change, the current design and operation of the radioactive liquid waste system will accommodate the effects of the proposed EPU. The existing equipment and plant procedures that control radioactive releases to the environment will continue to be used to maintain

radioactive liquid releases within the dose limits of 10 CFR 20.1302 and ALARA dose objectives in 10 CFR part 50, Appendix I.

Radioactive Solid Wastes

Radioactive solid wastes include solids recovered from the reactor coolant systems, solids that come into contact with the radioactive liquids or gases, and solids used in the reactor coolant system operation. The licensee evaluated the potential effects of the proposed EPU on the solid waste management system. The largest volume of radioactive solid waste is low-level radioactive waste, sources include resins and charcoal, sludges and spent filters from water processing, and dry active waste (DAW) that result from routine plant operation, refueling outages, and routine maintenance. DAW includes paper, plastic, wood, rubber, glass, floor sweepings, cloth, metal, and other types of waste generated during routine maintenance and outages.

The licensee states that the proposed EPU would not have a significant effect on the generation of radioactive solid waste volume from the primary reactor coolant and secondary side systems because system functions are not changing, and the volume inputs remain consistent with historical generation rates. The waste can be handled by the solid waste management system without modification. The equipment is designed and operated to process the waste into a form that minimizes potential harm to the workers and the environment. Waste processing areas are monitored for radiation, and safety features are in place to ensure worker doses are maintained within regulatory limits. The proposed EPU would not generate a new type of waste or create a new waste stream. Therefore, the impact from the proposed EPU on radioactive solid waste would not be significant.

Occupational Radiation Dose at the EPU Power Level

FPC stated that the in-plant radiation sources are expected to increase approximately linearly with the proposed increase in core power level of 15.5 percent. For the radiological impact analyses, the licensee assumed an increase to the licensed thermal power level from 2,609 MWt to 3,014 MWt or 15.5 percent. To protect the workers, the licensee's radiation protection program monitors radiation levels throughout the plant to establish appropriate work controls, training, temporary shielding, and protective equipment requirements so that worker doses will remain within the dose limits of 10 CFR Part 20 and ALARA.

In addition to the work controls implemented by the radiation protection program, permanent and temporary shielding is used throughout CR–3 to protect plant personnel against radiation from the reactor and auxiliary systems. The licensee determined that the current shielding design, which uses conservative analytical techniques to establish the shielding requirements, is adequate to offset the increased radiation levels that are expected to occur from the proposed EPU. The proposed EPU is not expected to significantly affect radiation levels within the plant and, therefore, there would not be a significant radiological impact to the workers.

Offsite Doses at the EPU Power Level

The primary sources of offsite dose to members of the public from CR–3 is radioactive gaseous and liquid effluents. The licensee provided a comparison of historic offsite dose levels at CR–3 with the projected post-EPU dose levels (bounded by a factor of two) and the Appendix I ALARA guidelines, as shown below in Table 4. The doubled post-EPU does levels remain less than one percent of the Appendix I ALARA guidelines.

TABLE 4— HISTORIC AND PROJECTED POST-EPU OFFSITE DOSES COMPARED TO 10 CFR PART 50, APPENDIX I ALARA GUIDELINES.

	Historic CR–3 offsite doses (200 to 2008)	Projected post-EPU offsite doses (x2 scaling)	Appendix I ALARA guidelines	Units
Liquid				
Total Body	9.39×10^{-5}	1.88×10^{-4}	3	mrem/yr.
Maximum Organ	3.65×10^{-3}	7.30×10^{-3}	10	mrem/yr.
Gaseous				
Gamma Air Dose	2.69×10^{-3}	5.38×10^{-3}	10	mrad/yr.
Beta Air Dose	1.95×10^{-2}	3.90×10^{-2}	20	mrad/yr.
Total Body	5.61×10^{-3}	1.10×10^{-2}	15	mrem/yr.
Maximum Organ	1.68×10^{-2}	3.36×10^{-2}	15	mrem/yr.

As previously discussed, operation at the EPU power level will not change the ability of the radioactive gaseous and liquid waste management systems to perform their intended functions. Also, there would be no change to the radiation monitoring system and procedures used to control the release of radioactive effluents in accordance with NRC radiation protection standards in 10 CFR Part 20 and 10 CFR Part 50, Appendix I.

Based on the above, the offsite radiation dose to members of the public would continue to be within NRC and EPA regulatory limits and, therefore, would not be significant.

Spent Nuclear Fuel

Spent fuel from CR–3 is currently stored in the plant's spent fuel pool, however, the licensee has initiated the construction of an independent spent fuel storage installation to provide additional dry storage of spent nuclear fuel at the CR–3 site. CR–3 is licensed to use uranium-dioxide fuel that has a maximum enrichment of 5 percent by weight uranium-235. The average fuel assembly discharge burnup for the proposed EPU is expected to be limited to 50,000 megawatt days per metric ton uranium (MWd/MTU) with no fuel pins exceeding the maximum fuel rod burnup limit of 60,000 MWd/MTU. The licensee's fuel reload design goals will maintain the CR–3 fuel cycles within the limits bounded by the impacts analyzed in 10 CFR Part 51, Table S–3—Uranium Fuel Cycle Environmental Data and Table S–4—Environmental Impact of Transportation of Fuel and Waste to and From One Light-Water-Cooled Nuclear Power Reactor, as supplemented by NUREG–1437, Volume 1, Addendum 1, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Main Report, Section 6.3—Transportation Table 9.1, Summary of findings on NEPA [National Environmental Policy Act] issues for

license renewal of nuclear power plants'' (ADAMS Accession No. ML12111A162). Therefore, there would be no significant impacts resulting from spent nuclear fuel.

Postulated Design-Basis Accident Doses

Postulated design-basis accidents are evaluated by both the licensee and NRC to ensure that CR–3 can withstand normal and abnormal transients and a broad spectrum of postulated accidents without undue hazard to the health and safety of the public.

The licensee performed analyses according to the Alternative Radiological Source Term methodology, updated with input and assumptions consistent with the proposed EPU. For each design-basis accident, radiological consequence analyses were performed using the guidance in NRC Regulatory Guide 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors'' (ADAMS Accession No. ML003716792). Accident-specific total effective dose equivalent was determined at the exclusion area boundary, at the low-population zone, and in the control room. The analyses also include the evaluation of the waste gas decay tank rupture event. The licensee concluded that the calculated doses meet the acceptance criteria specified in 10 CFR 50.67 and 10 CFR Part 50, Appendix A, General Design Criterion 19.

NRC is evaluating the licensee's EPU applications to independently determine whether they are acceptable to approve. The results of the NRC evaluation and conclusion will be documented in a Safety Evaluation Report that will be publicly available. If NRC approves the EPU, then the proposed EPU will not have a significant impact with respect to the radiological consequences of design-basis accidents.

Radiological Cumulative Impacts

The radiological dose limits for protection of the public and workers have been developed by the NRC and EPA to address the cumulative impact of acute and long-term exposure to radiation and radioactive material. These dose limits are codified in 10 CFR part 20 and 40 CFR part 190.

The cumulative radiation doses to the public and workers are required to be within the regulations cited above. The public dose limit of 25 millirem (0.25 millisieverts) in 40 CFR Part 190 applies to all reactors that may be on a site, the storage of low level radioactive waste and spent nuclear fuel, and includes any other nearby nuclear power reactor facilities. No other nuclear power reactor or uranium fuel cycle facility is located near CR–3. The offsite dose analysis data demonstrate that the dose to members of the public from radioactive effluents is well within the limits of 10 CFR Part 20 and 40 CFR Part 190. The projected post-EPU doses remain well within regulatory limits. Therefore, the NRC staff concludes that there would not be a significant cumulative radiological impact to members of the public from increased radioactive effluents from CR–3 at the proposed EPU power level.

As previously discussed, the licensee has a radiation protection program that maintains worker doses within the dose limits in 10 CFR Part 20 during all phases of CR–3 operations. The NRC expects continued compliance with regulatory dose limits during operation at the proposed EPU power level. Therefore, the NRC staff concludes that operation of CR–3 at the proposed EPU levels would not result in a significant impact to worker cumulative radiological dose.

Radiological Impacts Summary

As discussed above, the proposed EPU would not result in any significant radiological impacts. Table 5 summarizes the radiological environmental impacts of the proposed EPU at CR–3.

TABLE 5—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Radioactive Gaseous Effluents	Amount of additional radioactive gaseous effluents generated would be handled by the existing system.
Radioactive Liquid Effluents	Amount of additional radioactive liquid effluents generated would be handled by the existing system.
Radioactive Solid Waste	Amount of additional radioactive solid waste generated would be handled by the existing system.
Occupational Radiation Doses	Occupational doses would continue to be maintained within NRC limits.
Offsite Radiation Doses	Radiation doses to members of the public would remain below NRC and EPA radiation protection standards.
Spent Nuclear Fuel	The spent fuel characteristics will remain within the bounding criteria used in the impact analysis in 10 CFR Part 51, Table S–3 and Table S–4.
Postulated Design-Basis Accident Doses	Calculated doses for postulated design-basis accidents would remain within NRC limits.
Cumulative Radiological	Radiation doses to the public and plant workers would remain below NRC and EPA radiation protection standards.

Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC considered denial of the proposed EPU (i.e., the ''no-action'' alternative). Denial of the application would result in no change in the current environmental impacts. However, if the EPU was not approved for CR–3, other agencies and electric power organizations may be required to pursue other means, such as fossil fuel or alternative fuel power generation, in order to provide electric generation capacity to offset future demand. Construction and operation of such a fossil-fueled or alternative-fueled facility could result in impacts in air quality, land use, and waste management greater than those identified for the proposed EPU at CR–3. Furthermore, the proposed EPU does not involve environmental impacts that are significantly different from those originally indentified in the Crystal River Unit 3 FES and draft SEIS–44.

Alternative Use of Resources

This action does not involve the use of any different resources than those previously considered in the FES or draft SEIS–44.

Agencies and Persons Consulted

In accordance with its stated policy, on November 6, 2012, the NRC consulted with the State of Florida official regarding the environmental impact of the proposed action. The State official had no comments.

IV. Draft Finding of No Significant Impact

Based on the details provided in the EA, the NRC concludes that granting the proposed EPU license amendment is not

expected to cause impacts significantly greater than current operations. Therefore, the proposed action of implementing the EPU for CR–3 will not have a significant effect on the quality of the human environment because no significant permanent changes are involved, and the temporary impacts are within previously disturbed areas at the site and the capacity of the plant systems. Accordingly, the NRC has determined it is not necessary to prepare an environmental impact statement for the proposed action.

Dated at Rockville, Maryland, this 8th day of January, 2013.

For the Nuclear Regulatory Commission.

Jessie F. Quichocho,

Acting Chief, Plant Licensing Branch II–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–00781 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52–033; NRC–2008–0566]

DTE Electric Company (Formerly the Detroit Edison Company), Notice of Availability of Final Environmental Impact Statement for a Combined License for Unit 3 at the Enrico Fermi Atomic Power Plant Site

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Army Corps of Engineers, Detroit District, have published NUREG–2105, ''Final Environmental Impact Statement for the Combined License (COL) for Enrico Fermi Unit 3.'' The site is located in Monroe County, Michigan. The application for the COL was submitted by letter dated September 18, 2008, pursuant to part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR). A notice of receipt and availability of the application, which included the environmental report, was published in the **Federal Register** on October 10, 2008. A notice of acceptance for docketing of the COL application was published in the **Federal Register** on November 25, 2008. A notice of intent to prepare a draft environmental impact statement (EIS) and to conduct the scoping process was published in the **Federal Register** on December 10, 2008 (73 FR 75142).

SUPPLEMENTARY INFORMATION:

Accessing Information

Please refer to Docket ID NRC–2008–0566 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly-available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0566. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The four volumes of the final EIS are available electronically under ADAMS Accession Numbers ML12307A172, ML12307A176, ML12307A177, and ML12347A202.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

In addition, the final EIS can be accessed online at the NRC's Fermi Unit 3—specific Web page at *http://www.nrc.gov/reactors/new-reactors/col/fermi.html.* The Ellis Library and Reference Center, located at 3700 South Custer Road, Monroe, Michigan 48161–9716, has also agreed to make the final EIS available to the public.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Olson, Project Manager, Environmental Projects Branch 2, Division of New Reactor Licensing, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–3731; email: *Bruce.Olson@nrc.gov.*

Dated at Rockville, Maryland, this 10th day of January, 2013.

For the Nuclear Regulatory Commission.

Mark S. Delligatti,

Deputy, Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2013–00783 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–09415; NRC–2013–0006]

Aptuit, LLC; License Amendment Request, Opportunity To Provide Comments, Request a Hearing and To Petition for Leave To Intervene

AGENCY: Nuclear Regulatory Commission.

ACTION: Decommissioning plan, license amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

DATES: Comments must be filed by February 15, 2013. A request for a hearing must be filed by March 18, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publically available, by searching on *http://www.regulations.gov* under Docket ID NRC–2013–0006. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0006. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michael LaFranzo, Senior Health Physicist, Materials Control, ISFSI, and Decommissioning Branch, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission, 2443 Warrenville Road, Lisle, Illinois 60532; telephone: 630–829–9865; fax number: 630–515–1259; email: *Michael.LaFranzo@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2013–0006 when contacting the NRC about

the availability of information regarding this document. You may access information related to this document by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0006.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0006 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC) has received, by letter dated August 30, 2012, (ADAMS Accession Number ML12248A095) a proposed decommissioning plan and license amendment request from Aptuit, LLC requesting approval of the decommissioning plan for its facility located in Kansas City, Missouri. Specifically, the approval of the decommissioning plan would allow Aptuit, LLC to begin decommissioning work at the facility to make it suitable for release in accordance with NRC requirements in support of license termination.

An NRC administrative review, documented in a letter to the Licensee dated November 8, 2012, (ADAMS Accession Number ML12314A055) found the decommissioning plan acceptable to begin a technical review. If the NRC approves the amendment, the approval will be documented in an amendment to NRC License No 24–15595–01. However, before approving the proposed amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended, and the NRC's regulations. These findings will be documented in a Safety Evaluation Report and an Environmental Assessment and/or an Environmental Impact Statement.

III. Notice and Solicitation of Comments

In accordance with section 20.1405 of Title 10 of the *Code of Federal Regulations* (10 CFR), the Commission is providing notice and soliciting comments from local and State governments in the vicinity of the site and any Federally-recognized Indian tribe that could be affected by the decommissioning. This notice and solicitation of comments is published pursuant to § 20.1405, which provides for publication in the **Federal Register** and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site. Comments should be provided within 30 days of the date of this notice.

IV. Opportunity To Request a Hearing; Petitions for Leave To Intervene

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene with respect to the license amendment request. Requirements for hearing requests and petitions for leave to intervene are found in § 2.309, ''Hearing requests, Petitions to Intervene, Requirements for Standing, and Contentions.'' Interested persons should consult § 2.309, which is available at the NRC's Public Document Room (PDR), Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852 (or call the PDR at 1–800–397–4209 or 301–415–4737). The NRC's regulations are available online in the NRC Library at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

Any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. As required by § 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings the NRC must make to support the granting of a license amendment in response to the request. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the request for amendment that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the request for amendment fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's

belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with the NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Non-timely petitions for leave to intervene and contentions, amended petitions, and supplemental petitions will not be entertained absent a determination by the Commission, the Atomic Safety and Licensing Board or a Presiding Officer that the petition should be granted and/or the contentions should be admitted based upon a balancing of the factors specified in § 2.309(c)(1)(i)–(viii).

A State, county, municipality, Federally-recognized Indian tribe, or agencies thereof, may submit a petition to the Commission to participate as a party under § 2.309(d)(2). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by March 18, 2013. The petition must be filed in accordance with the filing instructions in Section V of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that State and Federally-recognized Indian tribes do not need to address the standing requirements in § 2.309(d)(1) if the facility is located within its boundaries. The entities listed above could also seek to participate in a hearing as a nonparty pursuant to § 2.315(c).

Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of § 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to such limits and conditions as may be imposed by the Atomic Safety and Licensing Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by March 18, 2013.

V. Electronic Submissions (E-Filing)

All documents filed in the NRC's adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under § 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an

exemption request, in accordance with § 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as Social Security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from January 16, 2013. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

Dated at Lisle, Illinois this 8th day of January 2013.

For the Nuclear Regulatory Commission.

Christine A. Lipa,

Chief, Materials Control, ISFSI, and Decommissioning Branch, Division of Nuclear Materials Safety, Region III.

[FR Doc. 2013–00786 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on February 7–8, 2013, 11545 Rockville Pike, Rockville, Maryland.

Thursday, February 7, 2013, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: Final Safety Evaluation Report Associated with the License Renewal Application for the Limerick Generating Station, Units 1 and 2 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and Exelon Corporation regarding the final safety evaluation report associated with the license renewal application for the Limerick Generating Station, Units 1 and 2.

10:45 a.m.–12:15 p.m.: Component Fabrication and Inspection of a Large Nuclear Steam Supply System (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff's approach for component fabrication and inspection of a large Nuclear Steam Supply System (NSSS).

1:15 p.m.–3:15 p.m.: Revised Construction Reactor Oversight Process Assessment Program (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the new Construction Reactor Oversight Process (CROP) pilot program plan applicable to oversight of new plants being constructed under the 10 CFR 50 process.

3:30 p.m.–7:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Friday, February 8, 2013, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:00 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. [**Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

10:00 a.m.–10:15 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

10:30 a.m.–7:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Antonio Dias, Cognizant ACRS Staff (Telephone: 301–415–6805, Email: *Antonio.Dias@nrc.gov*), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such

rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) Public Law 92–463, and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: January 10, 2013.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2013–00797 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS), Meeting of the ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Materials, Metallurgy & Reactor Fuels will hold a meeting on February 6, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, February 6, 2013—8:30 a.m. until 12:00 p.m.

The Subcommittee will review and discuss significant operating events and operating plan issues regarding the weld residual stress validation program. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: *Christopher.Brown@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: January 7, 2013.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–00792 Filed 1–15–13; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Privacy Act of 1974; Computer Matching Program Between the Office Of Personnel Management and Social Security Administration

AGENCY: Office of Personnel Management (OPM).

AGENCY: Notice-computer matching between the Office of Personnel Management and the Social Security Administration (CMA 1071).

SUMMARY: In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818 published June 19, 1989), and OMB Circular No. A–130, revised November 28, 2000, ''Management of Federal Information Resources,'' the Office of Personnel Management (OPM) is publishing notice of its new computer matching program with the Social Security Administration (SSA). This notice replacesthe notice that published in the **Federal Register** on January 8, 2013 (78 FR 1275).

DATES: OPM will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will

begin 30 days after the **Federal Register** notice has been published or 40 days after the date of OPM's submissions of the letters to Congress and OMB, whichever is later. The matching program will continue for 18 months from the beginning date and may be extended an additional 12 months thereafter. Subsequent matches will run until one of the parties advises the other in writing of its intention to reevaluate, modify, and/or terminate the agreement.

ADDRESSES: Send comments to Marc Flaster, Chief, Resource Management, Retirement Services, Office of Personnel Management, Room 4332, 1900 E. Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Bernard A. Wells III on (202) 606–2730.

SUPPLEMENTARY INFORMATION:

General

The Privacy Act (5 U.S.C. 552a), as amended, establishes the conditions under which computer matching involving the Federal government could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. Among other things, it requires Federal agencies involved in computer matching programs to:

Negotiate written agreements with the other agency for agencies participating in the matching programs;

Obtain the approval of the match agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

Furnish detailed reports about matching programs to Congress and OMB;

Notify applicants and beneficiaries that their records are subject to matching;

Verify match findings before reducing, suspending, termination or denying an individual's benefits or payments.

B. OPM Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of OPM's computer matching programs comply with the requirements of the Privacy Act, as amended.

Notice of Computer Matching Program, Office of Personnel Management (OPM) With the Social Security Administration (SSA)

Participating agencies:

OPM and SSA

B. Purpose of the Matching Program

The purpose of this agreement is to establish the terms, conditions and safeguards for disclosure of Social Security benefit information to OPM via direct computer link for the administration of certain programs by OPM's Retirement Services. OPM is legally required to offset specific benefits by a percentage of benefits (i.e. Disability Annuitants, Children Survivor Annuitants and Spousal Survivor Annuitants) payable under Title II of the Social Security Act. This matching activity will enable OPM to compute benefits at the correct rate and determine eligibility for these benefits.

C. Authority for Conducting the Matching Program

Section 8461 (h) of title 5 of the United States Code.

D. Categories of Records and Individuals Covered by the Match

Under the matching program, OPM will match SSA's disability insurance benefits (DIB) and payment date against OPM's records of retirees receiving a FERS disability annuity. The purpose of the matching program is to identify a person receiving both a FERS disability annuity and a DIB under Section 223 of the Social Security Act, 42 U.S.C. 423, in order to apply OPM offsets. Under FERS, 5 U.S.C. 8452(a)(2)(A), for any month in which an annuitant is entitled to both a FERS disability annuity and to a DIB, the FERS annuity shall be computed as follows: The FERS disability annuity is reduced, for any month during the first year after the individual's FERS disability annuity commences or is restored, by 100% of the individual's assumed Social Security DIB for such month, and, for any month occurring during a period other than the period described above, by 60% of the individual's assumed Social Security DIB for such month. OPM will provide SSA with an extract from the Annuity Master File and from pending claims snapshot records via the File Transfer Management System (FTMS). The extracted file will contain identifying information concerning the child survivor annuitant for whom OPM needs information concerning receipt of SSA child survivor benefits: full name, Social Security Number, date of birth, and type of information requested, as required to extract data from the SSA State Verification and Exchange System Files for Title II records. Each record on the OPM file will be matched to SSA's records to identify FERS child survivor annuitants who are receiving SSA CIBs. The SSA systems of records involved in this CMA are the Master Files of Social Security Number Holders and SSN Applications (Numident), 60–0058 and the MBR, 60–0090. OPM's system of records involved in this matching program is designated OPM/Central-1, Civil Service Retirement and Insurance Records. For records from OPM/Central-1, notice was provided by the publication of the system of records in the **Federal Register** at 64 FR 54930 (Oct. 8, 1999), as amended at 65 FR 2772 (May 3, 2000), updated at 72 FR 60041 (October 23, 2007), and amended at 73 FR 15013 (March 20, 2008).

OPM's records of surviving spouses who may be eligible to receive the FERS Supplementary Annuity will be matched against SSA's mother or father's insurance benefit and/or disabled widow(er)'s insurance benefit records. If the surviving spouse is receiving one of the above described Social Security benefits, he or she is not eligible to receive the FERS Supplementary Annuity. FERS, 5 U.S.C. 8442 (f) provides that a survivor who is entitled to a survivor's annuity and who meets certain other statutory requirements shall also be entitled to a Supplementary Annuity. To be eligible to receive a Supplementary Annuity for a given month, the surviving spouse of a deceased FERS annuitant must be eligible for a FERS survivor annuity, be under age 60, be an individual who would be entitled to widow's or widower's insurance benefits under the requirements of sections 202(e) and 402(f), based on the wages and self employment survivor had attained age 60 and otherwise satisfied necessary requirement for widow's or widow(er's) insurance benefits. See 5 U.S.C. 8442(f)(4)(B). The individual must not be eligible for Social Security mother's or father's insurance benefits or disabled widow(er)'s insurance benefits based on the deceased annuitant's wages and self employment income.

E. Privacy Safeguards and Security

The Privacy Act (5 U.S.C. 552a(o)(l)(G) requires that each matching agreement specify procedures for ensuring the administrative, technical, and physical security of the records matched and the results of such programs. All Federal agencies are subject to: the Federal Information Security Management Act of 2002 (FISMA) (44 U.S.C. 3541 *et seq.*); related

OMB circulars and memorandum (e.g. OMB Circular A–130 and OMB M–06–16); National Institute of Science and Technology (NIST) directives; and the Federal Acquisition Regulations (FAR). These laws, circulars, memoranda, directives and regulations include requirements for safeguarding Federal information systems and personally identifiable information used in Federal agency business processes, as well as related reporting requirements. OPM and SSA recognize that all laws, circulars, memoranda, directives, and regulations relating to the subject of this agreement and published subsequent to the effective date of this agreement must also be implemented if mandated. FISMA requirements apply to all Federal contractors and organizations or sources that process or use Federal information, or that operate, use, or have access to Federal information systems on behalf of an agency. OPM will be responsible for oversight and compliance of their contractors and agents. Both OPM and SSA reserve the right to conduct onsite inspection to monitor compliance with FISMA regulations.

F. Inclusive Dates of the Match

The matching program shall become effective upon signing of the agreement by both parties to the agreement and approval of the agreement by the Data Integrity Boards of the respective agencies, but no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget or 30 days after publication of this notice in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2013–00774 Filed 1–14–13; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2013–37; Order No. 1617]

International Mail Contracts

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request concerning an additional Global Plus 1C contract. This document invites public comments on the request and addresses several related procedural steps.

DATES: *Comments are due:* January 22, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Contents of Filing
III. Commission Action
IV. Ordering Paragraphs

I. Introduction

Notice of filing. On January 9, 2013, the Postal Service filed a notice announcing that it is entering into an additional Global Plus 1C contract (Agreement).[1] The Postal Service seeks to have the Agreement included within the Global Plus 1C product on the grounds of functional equivalence to a previously approved baseline agreement. *Id.* at 2.

Product history. The Commission added Global Plus 1C to the competitive product list by operation of Order No. 1151.[2] It concurrently designated the agreements filed in companion Docket Nos. CP2012–12 and CP2012–13 as the baseline agreements for purposes of establishing the functional equivalency of other agreements proposed for inclusion with the Global Plus 1C product. *Id.* at 7. The Agreement that is the subject of this filing is the immediate successor to the agreement approved in Docket No. CP2012–13. Notice at 4.

Customers for Global Plus 1C contracts are Postal Qualified Wholesalers (PQWs) and other large businesses that offer mailing services to end users for shipping articles via International Priority Airmail, International Surface Air Lift, Global Express Guaranteed, Express Mail International, Priority Mail International, and/or Commercial ePacket service. *Id.* at 5.

II. Contents of Filing

The filing includes the Notice, along with the following attachments:

- Attachment 1—a redacted copy of the Agreement;
- Attachment 2—a redacted copy of the certification required under 39 CFR 3015.5(c)(2);
- Attachment 3—a redacted copy of Governors' Decision No. 11–6; and
- Attachment 4—an application for non-public treatment of material filed under seal.

The material filed under seal consists of unredacted copies of the Agreement and supporting financial documents. *Id.* at 2. The Postal Service filed redacted versions of the sealed financial documents in public Excel spreadsheets. *Id.* at 3.

Functional equivalency. The Postal Service asserts that the instant Agreement and the baseline agreements are functionally equivalent because they share similar cost and market characteristics. *Id.* at 4. It notes that the pricing formula and classification established in Governors' Decision No. 08–8 ensure that each Global Plus 1C contract meets the criteria of 39 U.S.C. 3633 and related regulations. *Id.* at 4–5. The Postal Service also indicates that the pricing formula relied on for these Global Plus 1C contracts is included in Governors' Decision No. 11–6. *Id.* at 5. The Postal Service further asserts that the functional terms of the two agreements are the same and the benefits are comparable. *Id.*

The Postal Service states that prices may differ, depending on when an agreement is signed, due to updated costing information. *Id.* at 6. It also identifies other differences in contractual terms, but asserts that the differences do not affect either the fundamental service being offered or the fundamental structure of the Agreement.[3] *Id.* 5–6.

Effective date; term. The scheduled effective date of the Agreement is January 27, 2013. *Id.* at 3; Attachment 1 at 10. The Agreement is expected to be in effect for approximately 1 year. Termination is either the date prior to the date in January 2014 that Canada Post Corporation makes changes to published rates affecting Qualifying

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1C Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, January 9, 2013 (Notice). The Notice was filed in accordance with 39 CFR 3015.5. *Id.* at 1.

[2] Docket Nos. MC2012–6, CP2012–12, and CP2012–13, Order Adding Global Plus 1C to the Competitive Product List and Approving Related Global Plus 1C Agreements, January 19, 2012 (Order No. 1151).

[3] The list includes, among other things, the non-inclusion of a particular service, the addition and revision of articles, and related renumbering of articles. *See id.* at 6–7.

Mail[4] or, in the event of inaction, January 31, 2014. *Id.*

III. Commission Action

The Commission establishes Docket No. CP2013–37 for consideration of matters raised in the Notice. Interested persons may submit comments on whether the Agreement is consistent with the requirements of 39 CFR 3015.5 and the policies of sections 3632, 3633, and 3642. Comments are due no later than January 22, 2013. The public portions of the Postal Service's filing can be accessed via the Commission's Web site at *http://www.prc.gov.* Information on how to obtain access to nonpublic material appears at 39 CFR 3007.

The Commission appoints Curtis Kidd to represent the interests of the general public (Public Representative) in this case.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2013–37 for consideration of matters raised in the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission designates Curtis Kidd to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than January 22, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–00733 Filed 1–15–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2013–38; Order No. 1619]

International Mail Contracts

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request concerning an additional Global Plus 2C contract. This document invites public comments on the request and addresses several related procedural steps.

DATES: *Comments are due:* January 23, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Contents of Filing
III. Commission Action
IV. Ordering Paragraphs

I. Introduction

Notice of filing. On January 10, 2013, the Postal Service filed a notice announcing that it is entering into an additional Global Plus 2C contract (Agreement).[1] The Postal Service seeks to have the Agreement included within the Global Plus 2C product on the grounds of functional equivalence to previously approved baseline agreements. *Id.* at 2.

Background. The Commission added Global Plus 2 to the competitive product list, based on Governors' Decision No. 08–10, by operation of Order No. 112. *Id.* at 1. It later approved the addition of Global Plus 2C contracts to the competitive product list as a result of Docket No. MC2012–5.[2] The Commission designated the contracts filed in companion Docket Nos. CP2012–10 and CP2012–11 as the baseline agreements for purposes of establishing the functional equivalency of other agreements proposed for inclusion with the Global Plus 2C product. Notice at 2. The Agreement that is the subject of this filing is intended to be the immediate successor instrument to the agreement in Docket No. CP2012–10. *Id.* at 3.

Customers for Global Plus 2C contracts are Postal Qualified Wholesalers (PQWs) and other large businesses that offer mailing services to end users for shipping articles via Global Direct and/or International Business Reply Service. *Id.* at 6.

II. Contents of Filing

The filing includes the Notice, along with the following attachments:

- Attachment 1—a redacted copy of the Agreement;
- Attachment 2—a redacted copy of the certification required under 39 CFR 3015.5(c)(2);
- Attachment 3—a redacted copy of Governors' Decision No. 11–6; and
- Attachment 4—an application for non-public treatment of material filed under seal.

The material filed under seal consists of unredacted copies of the Agreement and supporting financial documents. *Id.* at 2. The Postal Service filed redacted versions of the sealed financial documents in public Excel spreadsheets. *Id.* at 3.

Functional equivalency. The Postal Service asserts that the instant Agreement and the baseline agreements are functionally equivalent because they share similar cost and market characteristics. *Id.* at 5. It notes that the pricing formula and classification established in Governors' Decision No. 08–10 ensure that each Global Plus 2C contract meets the criteria of 39 U.S.C. 3633 and related regulations. *Id.* The Postal Service also indicates that the pricing formula relied on for Global Plus 2C contracts is included in Governors' Decision No. 11–6. *Id.* The Postal Service further asserts that the functional terms of the two agreements are the same and the benefits are comparable. *Id.* at 6.

The Postal Service states that prices may differ, depending on when an agreement is signed, due to updated costing information. *Id.* It also identifies other differences in contractual terms, but asserts that the differences do not affect either the fundamental service being offered or the fundamental structure of the Agreement.[3] *Id.* at 6.

Effective date; term. The Agreement includes a scheduled effective date of January 14, 2013, however, given its filing date (January 10, 2013) and advance notice requirements,[4] the Agreement can take effect no sooner than January 25, 2013, assuming regulatory approval, creating a gap in coverage.[5]

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[4] Article 3 of the Agreement outlines the requirements for mail to be considered as Qualifying Mail. *Id.* at 2–3.

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 2C Contract Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, January 10, 2013 (Notice). The Notice was filed in accordance with 39 CFR 3015.5. *Id.* at 1.

[2] *See* Docket Nos. MC2012–5, CP2012–10, and CP2012–11, Order No. 1135, Order Adding Global Plus 2C to the Competitive Product List and Approving Functionally Equivalent Global Plus 2C Agreements, January 13, 2012.

[3] The list includes, among other things, the non-inclusion of a particular service, the addition and revision of articles, and related renumbering of articles. *See id.* at 7–8.

[4] Pursuant to 39 CFR 3015.5.

[5] The parties to the agreement in Docket No. CP2012–10, the same as to the instant Agreement, amended that agreement to extend its termination date to January 31, 2013. By separate motion, the Postal Service sought approval of that extension. *See* Motion of the United States Postal Service for

Continued

The Agreement is expected to be in effect for approximately 1 year. Termination is linked to either the date prior to the date in January 2014 that Canada Post Corporation takes action on price changes for certain domestic products [6] or, in the event of inaction, January 31, 2014. *Id.*

III. Commission Action

The Commission establishes Docket No. CP2013–38 for consideration of matters raised in the Notice. Interested persons may submit comments on whether the Agreement is consistent with the requirements of 39 CFR 3015.5 and the policies of sections 3632, 3633, and 3642. Comments are due no later than January 23, 2013. The public portions of the Postal Service's filing can be accessed via the Commission's Web site at *http://www.prc.gov.* Information on how to obtain access to nonpublic material appears at 39 CFR 3007.40.

The Commission appoints Curtis E. Kidd to represent the interests of the general public (Public Representative) in this case.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2013–38 for consideration of matters raised in the Postal Service's Notice.
2. Pursuant to 39 U.S.C. 505, the Commission designates Curtis E. Kidd to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.
3. Comments are due no later than January 23, 2013.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–00844 Filed 1–15–13; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2013–36; Order No. 1616]

International Mail Contracts

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request concerning an additional Global Plus 2C contract. This document invites public comments on the request and addresses several related procedural steps.

DATES: *Comments are due:* January 18, 2013.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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IV. Ordering Paragraphs

I. Introduction

Notice of filing. On January 8, 2013, the Postal Service filed a notice announcing that it is entering into an additional Global Plus 2C contract (Agreement).[1] The Postal Service seeks to have the Agreement included within the Global Plus 2C product on the grounds of functional equivalence to a previously approved baseline agreement. *Id.* at 2.

Background. Customers for Global Plus 2C contracts are Postal Qualified Wholesalers (PQWs) and other large businesses that offer mailing services to end users for shipping articles via Global Direct and/or International Business Reply Service. *Id.* at 6. The Commission added Global Plus 2 to the competitive product list, based on Governors' Decision No. 08–10, by operation of Order No. 112. *Id.* at 1. It later approved the addition of Global Plus 2C contracts to the competitive product list as a result of Docket No. MC2012–5.[2] The Commission designated the contracts filed in companion Docket Nos. CP2012–10 and CP2012–11 as the baseline agreements for purposes of establishing the functional equivalency of other agreements proposed for inclusion with the Global Plus 2C product. Notice at 2. The Agreement that is the subject of this filing is the immediate successor instrument to the agreement in Docket No. CP2012–11. *Id.* at 4.

II. Contents of Filing

The filing includes the Notice, along with the following attachments:

- Attachment 1—a redacted copy of the Agreement;
- Attachment 2—a redacted copy of the certification required under 39 CFR 3015.5(c)(2);
- Attachment 3—a redacted copy of Governors' Decision No. 11–6; and
- Attachment 4—an application for non-public treatment of material filed under seal.

The material filed under seal consists of unredacted copies of the Agreement and supporting financial documents. *Id.* at 2. The Postal Service filed redacted versions of the sealed financial documents in public Excel spreadsheets. *Id.* at 3.

Functional equivalency. The Postal Service asserts that the instant Agreement and the baseline agreements are functionally equivalent because they share similar cost and market characteristics. *Id.* at 5. It notes that the pricing formula and classification established in Governors' Decision No. 08–10 ensure that each Global Plus 2C contract meets the criteria of 39 U.S.C. 3633 and related regulations. *Id.* The Postal Service also indicates that the pricing formula relied on for these Global Plus 2C contracts is included in Governors' Decision No. 11–6. *Id.* The Postal Service further asserts that the functional terms of the two agreements are the same and the benefits are comparable. *Id.* at 5–6.

The Postal Service states that prices may differ, depending on when an agreement is signed, due to updated costing information. *Id.* at 6. It also identifies other differences in contractual terms, but asserts that the differences do not affect either the fundamental service being offered or the fundamental structure of the Agreement.[3] *Id.*

Effective date; term. The Agreement, as filed, includes a stated effective date of January 14, 2013; however, given its filing date (January 8, 2013) and advance notice requirements, the Agreement can take effect no sooner than January 23, 2013, assuming regulatory approval.[4] By operation of

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Temporary Relief and Notice of the United States Postal Service of Filing Modification to Global Plus 2C Negotiated Service Agreement, January 9, 2013 (Motion). By Order No. 1618, issued January 11, 2013, the Motion was granted.

[6] The products are domestic Lettermail, Incentive Lettermail, Admail, and/or Publications Mail products. Notice, Attachment 1 at 10.

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 2C Contract Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, January 8, 2013 (Notice). The Notice was filed in accordance with 39 CFR 3015.5. *Id.* at 1.

[2] *See* Docket Nos. MC2012–5, CP2012–10, and CP2012–11, Order No. 1135, Order Adding Global Plus 2C to the Competitive Product List and Approving Functionally Equivalent Global Plus 2C Agreements, January 13, 2012.

[4] This allows the Postal Service to satisfy the 15 days' advance notice requirement in 39 CFR 3015.5.

Order No. 1612, the Commission, at the Postal Service's request, extended the January 13, 2013 termination date of the original agreement to coincide with approval of the instant Agreement.[5] The extension avoids the gap in coverage that otherwise would occur.

The Agreement is expected to be in effect for approximately 1 year. Termination is linked to either the date prior to the date in January 2014 that Canada Post Corporation takes action on price changes for certain domestic products[6] or, in the event of inaction, a date certain (January 31, 2014). *Id.*

III. Commission Action

The Commission establishes Docket No. CP2013–36 for consideration of matters raised in the Notice. Interested persons may submit comments on whether the Agreement is consistent with the requirements of 39 CFR 3015.5 and the policies of 39 U.S.C. 3632, 3633, and 3642. Comments are due no later than January 18, 2013. The public portions of the Postal Service's filing can be accessed via the Commission's Web site at *http://www.prc.gov.* Information on how to obtain access to nonpublic material appears at 39 CFR 3007.40.

The Commission appoints James F. Callow to represent the interests of the general public (Public Representative) in this case.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2013–36 for consideration of matters raised in the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission designates James F. Callow to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than January 18, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2013–00719 Filed 1–15–13; 8:45 am]

BILLING CODE 7710–FW–P

[5] *See* Order No. 1612, Order Granting Motion for Temporary Relief, January 8, 2013.

[6] The products are domestic Lettermail, Incentive Lettermail, Admail, and/or Publications Mail products. Notice, Attachment 1 at 10.

PRESIDIO TRUST

Notice of Public Meeting of Fort Scott Council

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting of Fort Scott Council.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given that a public meeting of the Fort Scott Council (Council) will be held from 9:00 a.m. to 4:30 p.m. on Tuesday, January 29, 2013. The meeting is open to the public, but oral public comment will not be received at the meeting. Written comments may be submitted. The Council was formed to advise the Presidio Trust (Trust) Executive Director on matters pertaining to the rehabilitation and reuse of Fort Winfield Scott as a new national center focused on service and leadership development.

SUPPLEMENTARY INFORMATION: The Trust Executive Director, in consultation with the Chair of the Board of Directors, has determined that the Council is in the public interest and supports the Trust in performing its duties and responsibilities under the Presidio Trust Act, 16 U.S.C. 460bb appendix.

The Council will advise on the establishment of a new national center (Center) focused on service and leadership development, with specific emphasis on: (a) Assessing the role and key opportunities of a national center dedicated to service and leadership at Fort Scott in the Presidio of San Francisco; (b) providing recommendations related to the Center's programmatic goals, target audiences, content, implementation and evaluation; (c) providing guidance on a phased development approach that leverages a combination of funding sources including philanthropy; and (d) making recommendations on how to structure the Center's business model to best achieve the Center's mission and ensure long-term financial self-sufficiency.

Meeting Agenda: In this first meeting of the Council, members will establish the goals for the Council and begin to develop a strategic work plan including a timeline and milestones. In the morning session (approximately 9:00 a.m. to 12:30 p.m.) the Council will adopt bylaws and will discuss Council goals; in the afternoon session (approximately 1:30 p.m. to 4:30 p.m.) the Council will engage in a facilitated exercise regarding the Center's message and will develop a work plan.

Public Comment: Oral public comment will not be received at the meeting. Written comments may be submitted on cards that will be provided at the meeting, via mail to Laurie Fox, Presidio Trust, 103 Montgomery Street, P.O. Box 29052, San Francisco, CA 94129–0052, or via email to *fortscott@presidiotrust.gov.* If individuals submitting comments request that their address or other contact information be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently at the beginning of the comments. The Trust will make available for public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses.

Time: The meeting will be held from 9 a.m. to 4:30 p.m. on Tuesday, January 29, 2013.

Location: The meeting will be held in the Hawthorn Room of the Golden Gate Club, 135 Fisher Loop, Presidio of San Francisco.

For Further Information: Additional information is available online at *www.presidio.gov/fortscott.*

Dated: January 3, 2013.

Karen A. Cook,

General Counsel.

[FR Doc. 2013–00904 Filed 1–14–13; 4:15 pm]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68535; File No. SR–OCC–2012–24]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Its By-Laws and Rules Consistent With Recent System Changes to the Stock Loan/Hedge Program and Market Loan Program and Delete Certain Terms and Provisions No Longer Applicable

December 26, 2012.

Correction

In notice document 2012–31463, appearing on pages 140–142 in the issue of Wednesday, January 2, 2013, make the following correction:

On page number 142, in the third column, on the eighth and ninth lines from the bottom, the date reading ''January 23, 2012'' should read ''January 23, 2013''.

[FR Doc. C1–2012–31463 Filed 1–15–13; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68617; File No. SR–NASDAQ–2013–005]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the Latency Optics Add-on Service to QView

January 10, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 4, 2013, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish the Latency Optics add-on service to QView offered at no cost to subscribing members beginning February 4, 2013, and for a monthly fee beginning April 1, 2013.

The text of the proposed rule change is below. Proposed new language is *italicized.*

7058. QView

(a) QView is a web-based tool designed to give a subscribing member the ability to track its order flow on Nasdaq, and create both real-time and historical reports of such order flow. Members may subscribe to QView for a fee of $600 per month, per member firm.

(b) A QView subscriber may subscribe to the Latency Optics add-on service. Latency Optics is a web-based tool accessed through QView that provides a subscribing member the ability to monitor the latency of its order messages through its OUCH ports on the Nasdaq system in real-time, analyze the latency of messages sent to the Nasdaq system, and compare its latency to the average latency on the Nasdaq system at any given time. In addition users can view latency detail for order to book (i.e., how quickly an order is visible on the ITCH feed).

A member may subscribe to the Latency Optics add-on at no cost beginning February 4, 2013, and for a fee of $2,900 per month/per member beginning April 1, 2013. A Latency Optics subscription includes subscription to TradeInfo for up to 5 users at no additional cost beginning April 1, 2013.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt a new add on service to QView that provides a subscribing member firm with real-time order latency and analytical tools to measure the historical latency of the member firm's order messages sent to and from the NASDAQ Market Center (''System'') through the member firm's OUCH ports [3] and received on ITCH ports. Latency Optics, which is accessed through QView,[4] allows a subscribing member firm to view the latency of its orders, segregated by MPID and/or ports. The tool measures: (1) The roundtrip time that it takes from when an order enters the NASDAQ network to the time the acknowledgement is received back to the client edge; (2) the roundtrip time that it takes from when an order enters the NASDAQ network to the time that the order appears on the TotalView ITCH multicast feed; and (3) the roundtrip time that it takes from when an order cancel request enters the NASDAQ network to when the out message is received back to the client edge. The data provided by Latency Optics is displayed graphically and in table format, showing the latency experienced by the subscribing member firm for each of the three categories of latency for the current trading day, segregated by the firm's MPIDs and/or ports. The subscribing member firm may select an individual port to drill down to more detailed latency information concerning that port for the current trading day, including trade-by-trade latency data. The subscribing member firm may further drill down to more detailed information on one of the three individual latency categories for the individual port.

Latency Optics allows a subscribing member firm to set an alert when a certain latency threshold is reached in any of the three categories of latency measured. The thresholds for the alerts are determined by the subscribing member firm and are individually set by port, and the firm may elect to have the alert notifications provided hourly or at the end of the trading day.

The Exchange is proposing to offer the Latency Optics at no cost, other than subscription to QView and at least one subscription to TradeInfo,[5] on February 4, 2013. As noted, Latency Optics is an add-on service to QView, and as such a member firm must also subscribe to QView to access Latency Optics. In addition, a member firm that subscribes to QView, and by extension Latency Optics, must also have at least one TradeInfo subscription. TradeInfo allows a subscribing member firm to query for their [sic] orders submitted to the System and perform certain actions concerning the queried orders, such as canceling open orders. TradeInfo is the means by which a member firm accesses QView and Latency Optics. TradeInfo is offered complimentary as part of the NASDAQ Workstation or separately for a fee of $95 per user, per month. Each TradeInfo user account provides an access point to QView and Latency Optics, therefore a member firm that subscribes to multiple TradeInfo accounts may access both QView and Latency Optics through each of its TradeInfo user accounts concurrently. The Exchange is proposing to assess the monthly fee of $2,900 per member firm for Latency Optics, beginning on April 1, 2013, and which will include up to 5 monthly subscriptions to TradeInfo. Any TradeInfo subscriptions held by a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A port is a means by which a member firm may connect to the System. Ports are designated by the connection protocol used (e.g., OUCH, FIX, RASH).

[4] QView is a web-based, front-end application that allows a subscribing member firm to track all of its trading activity on the Exchange through detailed order and execution summaries. In addition, QView provides a subscribing member firm with statistics concerning the total number of executions, total volume, dollar value of executions, executions by symbol, add versus remove, buy versus sell, display versus non-display, number of open orders, use of routing strategies and liquidity code designation.

[5] TradeInfo allows a subscribing member firm to perform actions on their [sic] orders, such as querying all orders in a particular security or all orders of a particular type, regardless of their status (open, canceled, executed, etc.). For example, after querying for open orders the user is then able to select that open order and is allowed to make corrections to the order or cancel the order. *See* Rule 7015(f); *see also* Securities Exchange Act Release No. 55135 (January 19, 2007), 72 FR 3893 (January 26, 2007)(SR–NASDAQ–2006–062).

Latency Optics subscriber in excess of 5 will continue to be assessed the normal monthly subscription fee after April 1, 2013.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[6] in general, and Section 6(b)(4) of the Act,[7] in particular, because it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that NASDAQ operates or controls. The Latency Optics add-on service is voluntary and the subscription fee will be imposed on all purchasers equally. NASDAQ notes that Latency Optics is only available for a member firm's OUCH ports at this time. NASDAQ believes that it is equitable and not unfairly discriminatory to limit the add-on service to OUCH ports because the measure of latency monitored by the service is of greatest value to users of OUCH ports. OUCH is a NASDAQ proprietary protocol that is used by member firms to access the System as efficiently as possible.[8] For such OUCH port users, latency as measured by the Latency Optics service may be important in making investment decisions. Should a member firm wish to access the information provided by a Latency Optics subscription, it may subscribe to and trade via an OUCH port at any time, thus enabling it to subscribe to Latency Optics. NASDAQ may offer Latency Optics for other types of ports should there be member firm interest in expanding the add-on service to cover these ports. The proposed fee will be allocated to cover the costs associated with establishing the service, responding to customer requests, configuring NASDAQ systems, programming to user specifications, and administering the service, among other things, and may provide NASDAQ with a profit to the extent costs are covered.

The Exchange determined that the proposed fee is reasonable based on member firm interest in the service, costs associated with developing and supporting the service, and the value that the Latency Optics service provides to subscribing member firms. The information provided by the Latency Optics service relates to the subscribing member firm's order message activity through its OUCH ports, and is a measure of the speed at which such message activity is passing through in any given time. This information is valuable to member firms that rely on high connectivity speed to effectuate their trading strategies.

The Exchange believes the proposed rule change is consistent with Section 6(b)(5) of the Act,[9] which requires that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange believes the proposed rule change is consistent with these requirements because the proposed service provides a subscribing member firm with a useful analytical tool with which it may measure latency of order messages sent to, and received from, the System. With this information, a subscribing member firm will know what latency it is experiencing for a given order or execution on NASDAQ, and make more informed decisions based on this knowledge. Accordingly, the Exchange believes that the proposed service will further goals of the Act by providing a subscribing member firm with greater transparency with respect to latency it is experiencing in real-time through its connectivity to the System.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the proposed rule change will promote competition among Exchanges by encouraging them to provide their members with useful metrics concerning the latency experienced by their order messages, similar to Latency Optics. Such services would provide market participants with greater insight into the performance they receive from a particular market thus allowing them to make more informed investment decisions. As such, the Exchange believes that only competitor markets will be burdened by the proposed new service, as they may be forced to develop and offer a similar service to their members to remain competitive. The Exchange believes that this is appropriate in furtherance of the purposes of the Act because, by offering such services to its members, these competitor markets will allow a greater number of market participants to make more informed investment decisions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(ii) [sic] of the Act [10] and subparagraph (f)(6) of Rule 19b-4 thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved. The Exchange has provided the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] The OUCH protocol, unlike the FIX protocol for example, does not provide routing or special order instructions such as directed orders, or order types that check the NASDAQ book first and then route away to other destinations.

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(a)(ii) [sic].

[11] 17 CFR 240.19b-4(f)(6).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2013–005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–005. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2013–005, and should be submitted on or before February 6, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00791 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68616; File No. SR–NYSEArca–2012–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Withdrawal of Proposed Rule Change Proposing a Pilot Program To Create a Lead Market Maker Issuer Incentive Program for Issuers of Certain Exchange-Traded Products Listed on NYSE Arca, Inc.

January 10, 2013.

On April 27, 2012, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to create and implement, on a pilot basis, a Lead Market Maker Issuer Incentive Program for issuers of certain exchange-traded products listed on the Exchange. The proposed rule change was published for comment in the **Federal Register** on May 17, 2012.[3] The Commission initially received two comment letters on the proposal.[4] On June 20, 2012, the Commission extended the time period in which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change, to August 15, 2012.[5] The Commission subsequently received one additional comment letter on the proposed rule change.[6]

On July 11, 2012, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[7] The Commission thereafter received six comment letters and a response letter from the Exchange.[8] On October 2, 2012, the Commission issued a notice of designation of longer period for Commission action on proceedings to determine whether to disapprove the proposed rule change.[9] On January 9, 2013, the Exchange withdrew the proposed rule change (SR–NYSEArca–2012–37).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00790 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66966 (May 11, 2012), 77 FR 29419.

[4] *See* Letter from Gus Sauter, Managing Director and Chief Investment Officer, Vanguard, dated June 7, 2012; and Letter from Ari Burstein, Senior Counsel, Investment Company Institute, dated June 7, 2012.

[5] *See* Securities Exchange Act Release No. 67222 (June 20, 2012), 77 FR 38116 (June 26, 2012).

[6] *See* Letter from John T. Hyland, CFA, Chief Investment Officer, United States Commodity Funds LLC, dated June 27, 2012.

[7] *See* Securities Exchange Act Release No. 67411, 77 FR 42052 (July 17, 2012).

[8] *See* Letter from Joseph Cavatoni, Managing Director, and Joanne Medero, Managing Director, BlackRock, Inc., dated July 11, 2012; Letter from Stanislav Dolgopolov, Assistant Adjunct Professor, UCLA School of Law, dated August 15, 2012; Letter from James E. Ross, Global Head, SPDR Exchange Traded Funds, State Street Global Advisors, dated August 16, 2012; Letter from Ari Burstein, Senior Counsel, Investment Company Institute, dated August 16, 2012; Letter from F. William McNabb, Chairman and Chief Executive Officer, Vanguard, dated August 16, 2012; and Letter from Andrew Stevens, Legal Counsel, IMC Chicago, LLC d/b/a IMC Financial Markets, dated August 16, 2012. *See also* Letter from Janet McGinness, EVP & Corporate Secretary, General Counsel, NYSE Markets, dated August 14, 2012.

[9] *See* Securities Exchange Act Release No. 67962, 77 FR 61462 (October 9, 2012).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68536; File No. SR–SCCP–2012–02]

Self-Regulatory Organizations; Stock Clearing Corporation of Philadelphia; Notice of Filing of Proposed Rule Change With Respect to the Amendment of the By-Laws of Its Parent Corporation, The NASDAQ OMX Group, Inc.

December 26, 2012.

Correction

In notice document 2012–31464, appearing on pages 128–132 in the issue of Wednesday, January 2, 2013, make the following correction:

On page number 132, in the third column, on the thirteenth and fourteenth lines, the date reading ''January 23, 2012'' should read ''January 23, 2013''.

[FR Doc. C1–2012–31464 Filed 1–15–13; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68618; File No. SR–OCC–2012–801]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice, as Modified by Amendment No. 1 Thereto, in Connection With a Proposed Change To Enter Into an Unsecured, Committed Credit Agreement

January 10, 2013.

Pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i),[2] notice is hereby given that on December 18, 2012, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice described below. On December 21, 2012, OCC filed Amendment No. 1 to the advance notice.[3] The advance notice as amended by Amendment No. 1 is described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the advance notice and Amendment No. 1 from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

OCC is filing this advance notice in connection with a change to its operations (the ''Change'') in the form of entering into an unsecured, committed credit agreement (the ''Agreement'' or the ''Facility''). The Facility would provide OCC with access to additional liquidity for working capital needs and general corporate purposes. The Facility would also help satisfy the liquidity requirement of the Commodity Futures Trading Commission's (''CFTC'') regulation Section 39.11(e)(2).

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[4]

(A) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing and Settlement Supervision Act

Description of Change

The proposed Change would provide OCC with access to an unsecured, committed credit facility in an aggregate principal amount not to exceed $25 million. The Facility would be designed to provide OCC with access to additional liquidity for working capital needs and general corporate purposes. The Facility will also satisfy the liquidity requirement of CFTC regulation Section 39.11(e)(2).[5] OCC also does not expect any need to draw funds against the Facility. OCC's principal reason for entering into the Facility is to provide OCC additional flexibility in managing its liquid assets while ensuring continued compliance with the liquidity requirements of the CFTC regulations cited above.

Among other things, CFTC regulation Section 39.11(a)(2) requires a derivatives clearing organization (''DCO'') to hold an amount of financial resources that, at a minimum, exceeds the total amount that would enable the DCO to cover its operating costs for a period of at least one year, calculated on a rolling basis.[6] In turn, CFTC regulation Section 39.11(e)(2) provides that these financial resources must include unencumbered, liquid financial assets (*i.e.,* cash and/or highly liquid securities), equal to at least six months' operating costs and that if any portion of such financial resources is not sufficiently liquid, the DCO may take into account a committed line of credit or similar facility for the purpose of meeting this requirement.[7] Accordingly, under the proposed Change, OCC would enter into a credit agreement for the Facility with BMO Harris Bank N.A. (''Lender'') having a maximum aggregate principal loan amount not to exceed $25 million.

One of the conditions of OCC's access to the Facility is the execution of credit agreement documents between OCC and the Lender. OCC anticipates that the parties will finalize the forms of the credit agreement documents in early 2013. Ongoing conditions governing OCC's ability to access the Facility would include that no default or event of default by OCC may exist before or during an extension of credit by the Lender to OCC through the Facility and that certain representations of OCC must remain true and correct. Events of default would include, but not be limited to, failure to pay any interest, principal, fees or other amounts when due, default under any covenant or agreement in any loan document, materially inaccurate or false representations or warranties, cross default with other material debt agreements, insolvency, bankruptcy, dissolution or termination of the existence of OCC, and unsatisfied judgments.

The Facility would be available to OCC on a revolving basis for a 364-day term. Upon notice by OCC to the Lender of a request for funds, whether in writing or by telephone, the Lender would disburse loaned funds to OCC in U.S. dollars. The date of any loan would be required to be a business day, and the loans would be unsecured and made and evidenced by a promissory note provided by OCC. Under the terms of OCC's Agreement with the Lender, any loan proceeds would be required to be used by OCC to finance its working capital needs or for OCC's general corporate purposes. OCC's ability to draw against the Facility, even though no such draw is actually made, would contribute to OCC's compliance with the liquidity requirements prescribed by CFTC regulation Section 39.11(e)(2).

OCC would have the ability to terminate the Facility at any time. Termination within the first six months of the Facility would trigger a termination fee. After six months from the date of entering the Agreement with the Lender to establish the terms of the Facility, OCC would be permitted to cancel the Facility with no termination fee. Upon five days written notice during the term of the Facility, OCC would also be permitted to reduce the overall size of the Facility at any time. Any such reductions would be required to be made in an initial amount of at least $2.5 million. Thereafter, reductions would be able to be made in multiples of $1 million. In no event, however, would OCC be permitted to reduce the size of the Facility to an

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(i).

[3] Amendment No. 1 corrects Item 2 of OCC's Form 19b–4 to indicate that ''[t]he proposed change was approved by the Board of Directors of OCC at a meeting held on July 24, 2012,'' rather than September 25, 2012.

[4] The Commission has modified the text of the summaries prepared by OCC.

[5] For clarity concerning the scope of the proposed Change, OCC notes that the Commission recently published a notice of no objection to an OCC advance notice filing through which OCC replaced a separate credit facility that is maintained for the purpose of meeting obligations that may arise out of the default or suspension of an OCC clearing member or the failure of a bank or securities or commodities clearing organization to perform its obligations due to bankruptcy, insolvency, receivership, or suspension of operations. Securities Exchange Act Release No. 34–68002 (October 5, 2012); 77 FR 62308 (October 12, 2012).

[6] 17 CFR 39.11(a)(2).

[7] 17 CFR 39.11(e)(2).

amount that is less than the greater of either its aggregate principal amount of indebtedness outstanding with respect to loans from the Facility or $15 million.[8]

The outstanding principal balance of all loans made to OCC through the Facility will accrue interest equal to a base rate (generally equal to a Prime Rate, a Federal Funds Rate, or a LIBOR rate), as in effect from time to time, plus a certain applicable margin. Regardless of which method applies to a particular portion of OCC's total outstanding loan balance, in an event of a default the calculation of the amount of interest would be subject to a 2.00% increase above the otherwise applicable rate.

The Facility would involve a variety of customary fees payable by OCC to the Lender, including, but not limited to: (1) A one-time upfront fee payable at closing to the Lender calculated as a percentage of the total commitment amount of the Facility; (2) commitment fees payable quarterly in arrears on the average daily unused amount of the Facility; (3) reasonable out-of-pocket costs and expenses of the Lender in connection with the negotiation, preparation, execution, and delivery of the Facility and loan documentation, and costs and expenses in connection with any default, event of default, or enforcement of the Facility; and (4) termination fees if OCC elects to terminate the Facility prior to six months from the date of the credit agreement underlying the Facility.

Anticipated Effect on and Management of Risk

OCC believes that any impact of the Facility on the risks presented by OCC would be to reduce such risks by providing an additional source of liquidity for the protection of OCC, its clearing members, and the options market in general. OCC also believes it would provide OCC with additional liquidity for working capital needs and general corporate purposes and thereby assist OCC in satisfying the CFTC's requirements with respect to liquidity under CFTC regulation Section 39.11.

Like any lending arrangement, OCC notes there is a risk that the Lender would fail to fund when OCC requests a loan, because of the Lender's insolvency, operational deficiencies, or otherwise. Even if OCC were to draw on the Facility for liquidity purposes, which it does not anticipate, OCC believes that the potential funding risk associated with the Facility is mitigated in several ways. First, the Lender is a national banking association that is subject to oversight by prudential banking regulators with respect to its safety and soundness and its ability to meet its lending obligations. Furthermore, the $25 million size of the Facility would be relatively small when compared to the total resources available to OCC. Therefore, if the Facility proved unavailable to OCC for any reason, OCC believes that it readily would be able to access, or arrange for access, to other sources of liquidity if necessary.

According to OCC, a second risk associated with the Facility is the risk that OCC would default on its obligation to make timely payment of principal or interest. OCC believes the benefits of the Facility outweigh this risk. Finally, because the Facility would be an unsecured lending arrangement, OCC would not be at risk in an event of default of the Lender potentially liquidating OCC assets that are used to secure loaned funds.

(B) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The clearing agency may implement the proposed change pursuant to Section 806(e)(1)(G) of the Clearing Supervision Act[9] if it has not received an objection to the proposed change within 60 days of the later of (i) the date that the Commission received the advance notice or (ii) the date the Commission receives any further information it requests for consideration of the notice. The clearing agency shall not implement the proposed changes contained in the advance notice if the Commission objects to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date of receipt of the advance notice, or the date the Commission receives any further information it requested, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed. The clearing agency shall post notice on its Web site of proposed changes that are implemented.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2012–801 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2012–801. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.theocc.com/about/publications/bylaws.jsp.*

All comments received will be posted without change; the Commission does not edit personal identifying

[8] In the event that OCC seeks to terminate or reduce the overall size of the Facility, OCC will first file an advance notice with the Commission.

[9] 12 U.S.C. 5465.

information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OCC–2012–801 and should be submitted on or before February 6, 2013.

By the Commission.

Kevin O'Neill,

Deputy Secretary.

[FR Doc. 2013–00795 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68519; File No. SR–NASDAQ–2012–143]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Extension of the Exchange's Penny Pilot Program and Replacement of Penny Pilot Issues That Have Been Delisted

December 21, 2012.

Correction

In notice document 2012–31462, appearing on pages 136–138 in the issue of Wednesday, January 2, 2013, make the following correction:

On page number 138, in the second column, on the forty-first line, the date reading ''January 23, 2012'' should read ''January 23, 2013''.

[FR Doc. C1–2012–31462 Filed 1–15–13; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68620; File No. SR–CHX–2012–20]

Self Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Alter Exchange Rules and Fee Schedule Relating to Annual Listing Maintenance Fees

January 10, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 31, 2012, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend Exchange Rules and its Schedule of Participant Fees and Assessments (the ''Fee Schedule'') to alter fees relating to listings. The Exchange proposes to implement the fee change on January 1, 2013. The text of this proposed rule change is available on the Exchange's Web site at *http://www.chx.com/rules/proposed_rules.htm,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its listings rules and Fee Schedule to revise its existing annual listing maintenance fee. The Exchange proposes to make the fee change operative on January 1, 2013 as its listing maintenance fee is assessed annually on that date. Should the proposed fee changes take effect after January 1, 2013, the Exchange notes that it will fail to benefit from significant revenue associated with the proposed fee change.

Currently, the Exchange imposes an annual listing maintenance fee of $1 per 20,000 shares to maintain listings. Under the existing rules, the Exchange imposes a minimum annual maintenance fee of $1,250 but also caps the fee at a maximum annual maintenance fee of $3,000. The Exchange proposes to keep its current minimum annual maintenance fee at $1,250 but to increase its maximum annual maintenance fee to $5,000. The change is proposed to increase revenue to the Exchange [3] and to defray the costs associated with supporting the listing program. The Exchange proposes increasing the maximum annual maintenance fee to better compensate the Exchange for those listings that incur greater costs.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act [4] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act [5] in particular because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, or broker dealers.

The Exchange believes that the change is reasonable because the increased revenue from the fee change will defray costs associated with supporting its listing program. Further, the Exchange believes that increasing the cap on the annual listing maintenance fee is a reasonable and equitable solution as many of the costs associated with the listing program are associated with the maintenance of currently listed companies. Furthermore, while the Exchange believes that the minimum annual listing maintenance fee of $1,250 compensates it, at this time, for the fixed costs associated with maintaining any listing, the variable costs associated with larger or additional listings can be much higher and, as such, the Exchange believes it is reasonable to raise the annual maintenance fee cap. The Exchange notes that the fee change is reasonable in comparison to continuing annual listing fees at certain other U.S. Equities exchanges.[6]

The Exchange also believes that the proposed change is not unfairly discriminatory because the proposed fee changes are directly related to those current CHX listings that incur additional costs to the Exchange. For example, a large CHX listing incurs additional costs to the Exchange's listing department though it may qualify for the maximum annual maintenance fee cap. The Exchange believes that raising the annual maintenance fee cap

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that the Exchange has represented that the increased revenue from the fee change will defray costs associated with supporting its listing program. *See* ''Statutory Basis'' *infra.*

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4) and (5).

[6] *See* NYSE Arca, Nasdaq, and BATS listing fees for differing calculations.

is an equitable and non-discriminatory way to directly recuperate the increased ongoing costs associated with those listings that are primarily responsible for such costs. In raising its maximum annual listing maintenance fee, the Exchange will receive revenue from continuing listings and thereby directly aid in supporting its listing program.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The rule change is designed to raise the annual maintenance fee cap as an equitable and non-discriminatory way to directly recuperate the increased ongoing costs associated with those listings that are primarily responsible for such costs. As those listings incur additional costs to the Exchange, the Exchange believes that the proposed rule change more fairly allocates costs associated with this activity. The Exchange therefore believes that the rule change does not impose a disparate burden on competition either among or between classes of market participants. As stated above, the proposed change will raise revenue to the Exchange and defray costs associated with continuing to support its listing program. Further, supporting a listing program on an exchange benefits competition in the industry as market participants have choices, including the option to list on that exchange. In addition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change promotes a competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [7] of the Act and subparagraph (f)(2) of Rule 19b–4 [8] thereunder, because it establishes a due, fee, or other charge imposed by CHX.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CHX–2012–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2012–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549–1090, on official business days between 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the CHX's principal office and on its Internet Web site at *www.chx.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2012–20 and should be submitted on or before February 6, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00771 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68615; File No. SR–CBOE–2012–133]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Codify in the CBOE Stock Exchange Rules a Cross Order Type Tied to a Related Derivative Component

January 10, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 31, 2012, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to codify in its rules the availability of a cross order type tied to a related derivative component on CBOE Stock Exchange (''CBSX''). The text of the proposed rule change is provided below.

(additions are italicized; deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

CHAPTER L—CBOE Stock Exchange (CBSX) Rules

* * * * *

Rule 51.8 Types of Orders Handled

At the discretion of CBSX, and once the CBSX System is so enabled, any of the following types of orders may be accommodated on the CBSX System:

* * * * *

(u) Tied Cross Only Order. A Tied Cross Only Order is an order to trade the stock component of a qualified contingent trade which meets the qualified contingent trade exemption pursuant to Rule 611(d) of Regulation NMS under the Exchange Act. A Tied Cross Only Order may be executed without regard to the protected NBBO. The order may only be executed against a contra Tied Cross Only Order for the same size and price and may only be executed at prices at or within the CBSX BBO and, when at the CBSX BBO, consistent with the requirements of Rule 52.11.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Contingent trades play an important role in the investment and trading strategies of investors and the securities industry generally. A contingent trade is a multi-component trade involving orders for a security and a related derivative, or, in the alternative, orders for related securities, that are executed at or near the same time. The financial instruments in a contingent trade may be equities, options, futures, bonds, and combinations thereof. The economics of the transaction are based on the relationship between the prices of the security and the related derivative, or between the prices of the related securities, and the execution of one order is contingent upon the execution of the other order(s). The sought-after spread or ratio between the relevant instruments is known and specified at the time of order placement, and this sought-after spread or ratio stands regardless of the prevailing price at the time of execution. Therefore, the parties to these transactions are focused on the net price of the transaction for all of the component instruments, rather than on the absolute price of any single component instrument. Indeed, with this focus on the relative prices of the component instruments to a contingent trade, the price of a component of a particular trade may or may not correspond to the prevailing market price of the security. The parties to the trade will not execute one side of the trade without the other component or components being executed in full (or in ratio) and at the specified spread or ratio.[3]

The Commission noted that qualified contingent trades potentially could become too risky and costly to be employed successfully if they were required to meet the trade-through provisions of Rule 611 of Regulation NMS under the Securities Exchange Act of 1934 (the ''Exchange Act''). Absent an exemption, participants in contingent trades often would need to use the Rule's intermarket sweep order exception and route orders to execute against protected quotations with better prices than an NMS stock component of the contingent trade. Any executions of these routed orders could throw the participants ''out of hedge'' and necessitate additional transactions in an attempt to correct the imbalance. As a practical matter, the difficulty of maintaining a hedge, and the risk of falling out of hedge, could dissuade participants from engaging in contingent trades, or at least raise the cost of such trades. The elimination or reduction of this trading strategy potentially could remove liquidity from the market.[4]

Due to the above reasons, on August 31, 2006, pursuant to Rule 611(d) of Regulation NMS, the Commission granted an exemption from the provisions of Rule 611 of Regulation NMS to each NMS stock component of certain qualified contingent trades (as defined in the exemptive order) (the ''QCT Exemption'').[5] On April 4, 2008, pursuant to Rule 611(d) of Regulation NMS under the Exchange Act, the Commission issued an order modifying the QCT Exemption.[6]

In addition to incorporating several exceptions codified in Rule 611(b) of Regulation NMS, CBSX Rule 52.7 also incorporates exemptions from the Order Protection Rule granted by Commission Order.[7] The Exchange now wishes to further clarify that the CBSX System accommodates Tied Cross Only Orders, which are orders to trade the stock component of a qualified contingent trade (that qualifies for the QCT Exemption) on CBSX pursuant to Rule 611 of Regulation NMS under the Exchange Act, as approved by the Commission and as may be amended by the Commission pursuant to Rule 611(d) of Regulation NMS.

The following examples will explain how Tied Cross Only Orders trade on CBSX:

The NBBO in stock ABC is $10.00–$10.01 (5 × 5), while CBSX is quoting $9.99—$10.02 (1 × 1). CBSX receives a Tied Cross Only Order to cross 10,000 shares at $10.03 (consisting of an order to buy 10,000 shares at $10.03 and an order to sell 10,000 shares at $10.03). Since the order pair is priced outside the CBSX book, the order will be cancelled

Consider now, in example 2, a situation in which the NBBO is $10.00–$10.01 (5 × 5), while CBSX is quoting $9.99—$10.02 (2 × 2). CBSX receives a Tied Cross Only Order to cross 10,000 shares at $10.02 (consisting of an order to buy 10,000 shares at $10.02 and an order to sell 10,000 shares at $10.02). The Tied Cross Only Order received is also greater in size than any single public customer order currently resting on the CBSX Book at $10.02. As a Tied Cross Only Order is a qualified contingent trade meeting the QCT Exemption, a trade-through is permitted and the shares will not be routed to external markets. Rather, the buy order will trade directly against the sell order at $10.02, provided that the order meets the requirements of CBSX Rule 52.11.

[3] Letter to Nancy M. Morris, Secretary, Commission, from Andrew Madoff, SIA Trading Committee, SIA, dated June 21, 2006 (''SIA Exemption Request''), page 2.

[4] *See* Exchange Act Release No. 54389 (August 31, 2006), page 7–8.

[5] *See* Exchange Act Release No. 54389 (August 31, 2006).

[6] *See* Exchange Act Release No. 57620 (April 4, 2008).

[7] *See* CBSX Rule 52.7(a)(9).

CBSX Rule 52.11 provides that a CBSX Trader may cross two original orders at the established bid or offer irrespective of existing interest at such bid/offer so long as the cross transaction is (i) for at least 5,000 shares; (ii) is for a principal amount of at least $100,000; and (iii) is greater in size than any single public customer order resting on the CBSX Book at the proposed cross price. In this example, the Tied Cross Only Order meets all three criteria; the order is for 10,000 shares, is for the principal amount of $100,200 and is greater in size than any single public customer order currently resting on the CBSX Book at the proposed cross price. Therefore, the buy order will trade against the sell order at $10.02

In this third example, the NBBO is $10.00–$10.01 (5 × 5), while CBSX is quoting $9.99–$10.02 (2 × 2). CBSX receives a Tied Cross Only Order to cross 9,000 shares at $10.02 (consisting of an order to buy 9,000 shares at $10.02 and an order to sell 9,000 shares at $10.02). The Tied Cross Only Order received is also greater in size than any single public customer order currently resting on the CBSX Book at $10.02. In this scenario however, the Tied Cross Only Order does not meet all the requirements of Rule 52.11. Although the order is for over 5,000 shares and is greater than any single customer order on the CBSX book at $10.02, it is for a principal amount of only $90,180, which is less than the required $100,000. Consequently, if there is any existing interest at the proposed cross price resting on the CBSX Book, the Tied Cross Only Order will be cancelled.

In this final example, the NBBO is $10.00–$10.01 (5 × 5), while CBSX is quoting $9.99—$10.03 (2 × 2). CBSX receives a Tied Cross Only Order to cross 10,000 shares at $10.02 (consisting of an order to buy 10,000 shares at $10.02 and an order to sell 10,000 shares at $10.02). In this example, the order pair is priced within the CBSX BBO. Accordingly, the buy order would cross against the sell order at 10,000 shares at $10.02.

Finally, it should be noted that it is incumbent on the user placing a Tied Cross Only Order to represent to the Exchange that the transaction meets the QCT exemption.

The Exchange believes that the codification of this order type will clarify that CBSX accommodates market participants with flexibility in executing transactions that meet the specific requirements of this order type.

2. *Statutory Basis*

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder and, in particular, the requirements of Section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. Tied Cross Only Orders provide investors with an additional tool to facilitate the execution of qualified contingent trades, a type of trade recognized by the Commission as beneficial to market participants. The clarification that CBSX accommodates this order type should clear up any possible confusion and therefore inform investors. Further, the proposed rule change is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, in that all such investors may enter Tied Cross Only Orders.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed rule change merely codifies the availability of a cross order type tied to a related derivative component. As discussed above, Tied Cross Only Orders are orders to trade the stock component of a qualified contingent trade, a type of trade already recognized by the Commission as beneficial to market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)[10] of the Act and Rule 19b–4(f)(6)[11] thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2012–133 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2012–133. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE.,

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2012–133 and should be submitted on or before February 6, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00789 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68619; File No. SR–BATS–2012–044]

Self-Regulatory Organizations; BATS Exchange, Inc.; Order Granting Approval of Proposed Rule Change to Amend BATS Rule 14.11, Entitled ''Other Securities,'' and To List and Trade Shares of Certain ProShares Products

January 10, 2013.

I. Introduction

On November 5, 2012, BATS Exchange, Inc. (''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend BATS Rule 14.11, entitled ''Other Securities,'' and to list and trade shares of certain ProShares products. The proposed rule change was published for comment in the **Federal Register** on November 26, 2012.[3] The Commission received no comments on the proposal. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend its rules to allow listing of certain exchange-traded products based on provisions substantially similar to those on NYSE MKT LLC (formerly the American Stock Exchange LLC or ''AMEX'') and NYSE Arca Equities, Inc. (''NYSE Arca''). Specifically, the Exchange proposes to modify BATS Rule 14.11(f), which governs the listing of Trust Issued Receipts (''TIRs''), to adopt new criteria for listing TIRs that invest in ''Investment Shares'' or ''Financial Instruments,'' as proposed to be defined. The Exchange proposes to add subparagraph (4) to Rule 14.11(f). The proposed subparagraph (4) is based on Commentary .07 of AMEX Rule 1202 and Commentary .02 of NYSE Arca Rule 8.200 and is intended to accommodate future listing and trading of TIRs that invest in Investment Shares or Financial Instruments. Any new listing or trading of an issue of such TIRs, however, will be subject to the approval of a proposed rule change by the Commission pursuant to Section 19(b)(2) of the Act[4] and Rule 19b–4 thereunder.[5] In addition, the Exchange proposes to amend Rule 14.11 to allow TIRs to trade until the end of the Exchange's after market session, which ends at 5:00 p.m. E.T.,. The Exchange also proposes to make certain changes so that its rules conform to the listing rules of other exchanges and to make certain non-substantive changes and corrections to existing rule text.

In addition to the above enumerated proposed changes, the Exchange further proposes to list and trade shares (''Shares'') of the following pursuant to proposed Rule 14.11(f): ProShares Managed Futures Strategy; ProShares Commodity Managed Futures Strategy; and ProShares Financial Managed Futures Strategy (each a ''Fund,'' and together, ''Funds'').[6] Each Fund is a series of the ProShares Trust II (''Trust''), a Delaware statutory trust. ProShare Capital Management LLC (''Sponsor'') is the Trust's Sponsor, and Wilmington Trust Company is the Trust's trustee. Brown Brothers Harriman & Co. serves as the administrator (''Administrator''), custodian, and transfer agent of the Funds. SEI Investments Distribution Co. serves as distributor of the Shares.[7]

Proposed Listing Rules

The Exchange proposes to adopt definitions for the terms ''Investment Shares,'' ''futures contract,'' ''forward contract,'' and ''Financial Instruments'' for purposes of Rule 14.11(f)(4).[8]

The proposed listing requirements include a designation requirement. Specifically, the proposed rules provide that the Exchange may list and trade TIRs investing in Investment Shares or Financial Instruments and that each issue of a TIR based on a particular Investment Share or Financial Instrument shall be designated as a separate series and identified by a unique symbol.

When the Exchange is the primary listing exchange for a trust that issues TIRs that invest in Investment Shares or Financial Instruments, the trust will be subject to the initial and continued listing criteria under proposed Rule 14.11(f)(4), as well as Rules 14.11(f)(1) and (2), as proposed to be amended. In particular, the proposed initial listing criteria provide that the Exchange will establish a minimum number of receipts required to be outstanding at the time of commencement of trading on the Exchange. The proposed continued listing criteria provide that the Exchange may consider delisting or removal from listing TIRs under any of the following circumstances:

- If following the initial twelve month period following the commencement of trading of the receipts, (1) the trust has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of TIRs for 30 or more consecutive trading days; (2) the trust has fewer than 50,000 receipts issued and outstanding; or (3) the market value of all receipts issued and outstanding is less than $1 million.
- If the level or value of an underlying index or portfolio is no longer calculated or available on at least a 15-second delayed basis or the Exchange stops providing a hyperlink on its Web site to any such asset or investment value.
- If the Intraday Indicative Value (''IIV'') is no longer made available on at least a 15-second delayed basis.
- If such other event shall occur or condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

In addition, the Exchange will remove TIRs from listing and trading upon termination of a trust. A trust may terminate in accordance with the provisions of the trust prospectus,

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[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 68257 (November 19, 2012), 77 FR 70500 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] 17 CFR 240.19b–4.

[6] *See* the Trust's Registration Statement on Form S–1, dated November 29, 2011, as amended (File No. 333–178212) (''Registration Statement'').

[7] The Commission approved the listing and trading of shares of the Funds on NYSE Arca. *See* Securities Exchange Act Release No. 66334 (February 6, 2012), 77 FR 7219 (February 10, 2012) (SR–NYSEArca–2011–94) (order approving NYSE Arca listing and trading of the Shares of the Funds). Although the Shares of the Funds were approved for listing and trading on NYSE Arca, the Shares have not commenced trading.

[8] *See* Notice, *supra* note 3, for more information on the proposed defined terms.

which may provide for termination if the value of securities in the trust falls below a specified amount. The Exchange represents that it prohibits the initial and/or continued listing of any security that is not in compliance with Rule 10A–3 under the Exchange Act.[9]

Further, the Exchange proposes to require that the term of a trust shall be as stated in the prospectus; however, such entity may be terminated earlier under such circumstances as may be specified in the prospectus. The Exchange also proposes to add the defined term ''Trustee'' to Rule 14.11(f)(1), along with certain requirements for the Trustee.[10]

The Exchange also proposes to add to Rule 14.11 a new subparagraph (f)(4)(C)(v), which states that voting rights shall be as set forth in the applicable trust prospectus.

In addition, the Exchange proposes a new sub-paragraph (D), which sets forth certain restrictions on Members acting as registered Market Makers in TIRs that invest in Investment Shares or Financial Instruments to facilitate surveillance. Rule 14.11(f)(4)(D)(i) will require that a registered Market Maker in TIRs must file with the Exchange, in a manner prescribed by the Exchange, and keep current, a list identifying all accounts for trading the underlying physical asset or commodity, related futures or options on futures, or any other related derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. The rule will also prohibit a registered Market Maker in the TIRs from trading in the underlying physical asset or commodity, related futures or options on futures, or any other related derivatives, in an account in which the registered Market Maker, directly or indirectly, controls trading activities or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by the rule. Finally, Rule 14.11(f)(4)(D)(ii) will require that Market Makers handling shares of TIRs provide the Exchange with such books, records, or other information pertaining to transactions in the same, as may be requested by the Exchange.

The Exchange also proposes to adopt Rule 14.11(f)(4)(E) related to limitation of liability.[11] The Exchange further proposes to adopt Rule 14.11(f)(4)(F), which would require the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading TIRs based on separate Investment Shares or Financial Instruments.

In addition to the new subparagraph (f)(4) to Rule 14.11, the Exchange proposes to make additional substantive modifications to Rule 14.11(f) in order to conform to AMEX and NYSE Arca rules related to TIRs. First, the Exchange proposes to delete current subparagraph (f)(2)(B) of Rule 14.11, which sets forth criteria that are not included in the equivalent TIR rules of AMEX (AMEX Rule 1202) and NYSE Arca (NYSE Arca Rule 8.200). Subparagraph (f)(2)(B) of Exchange Rule 14.11 governs the eligibility of certain component securities that have already been included as component securities in the applicable series of TIRs or have been received as part of a merger, consolidation, corporate combination, or other event. Rather than apply different criteria to such securities, the Exchange proposes to apply the criteria of Rule 14.11(f)(2)(G) (to be re-numbered as (f)(3)) to all component securities of a TIR listed on the Exchange. Since this change will help to align the Exchange's rules applicable to TIRs with the rules of AMEX and NYSE Arca, it should help to alleviate confusion amongst issuers.

Second, in order to align the Exchange's rules with NYSE Arca Rule 8.200, the Exchange proposes to eliminate the requirement of current Rule 14.11(f)(2)(E)(iv) that the Exchange receive prior notice and provide approval before a change can be made to the trustee of a listed TIR

Third, the Exchange proposes to eliminate the requirement in Rule 14.11(f)(2)(F) that transactions in TIRs may only be made in round lots of 100 receipts or round lot multiples. As with the proposed changes above, this change will align the Exchange's rules with AMEX Rule 1202 and NYSE Arca Rule 8.200, which do not limit transactions in TIRs to round lots. Further, to the extent a specific TIR should be limited to trading in round lots, the Exchange has general authority pursuant to Exchange Rule 11.2 to limit transactions accordingly.[12]

The Exchange also proposes certain other technical changes, which can be found in the Notice.[13]

Trading Rules

The Exchange deems the TIRs to be equity securities, thus rendering trading in the securities subject to the Exchange's existing rules governing the trading of equity securities. The TIRs will trade on the Exchange from 8:00 a.m. to 5:00 p.m. E.T. (Pre-Opening Session, Regular Trading Hours, and After Hours Trading Session). The Exchange represents that it has appropriate rules to facilitate transactions in the TIRs during all trading sessions. The minimum price increment for quoting and entry of orders in equity securities traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price increment for order entry is $0.0001.[14]

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the TIRs. The Exchange represents that it will halt trading in the TIRs under the conditions specified in BATS Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the TIRs inadvisable. These may include: (1) The extent to which trading is not occurring in the TIRs and/or the underlying asset or assets; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. If any of the IIV, the level of the underlying index, or the value of the underlying assets of the TIRs is not disseminated as required, the Exchange may halt trading during the day in which such interruption to the dissemination occurs. If an interruption to the dissemination of the IIV, the level of the underlying index, or the value of the underlying assets of the TIRs persists past the trading day in which it occurred, the Exchange represents that it will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the Net Asset Value (''NAV'') with respect to a series of the TIRs is not disseminated to all market participants at the same time, it represents that it will halt trading in such series until such time as the NAV is available to all market participants.

Surveillance

The Exchange represents that its surveillance procedures are adequate to address any concerns about the trading

[9] 17 CFR 240.10A–3.

[10] *See* Notice, *supra* note 3, for more information on such requirements for the Trustee.

[11] *See* Notice, *supra* note 3, for additional details on the proposed provision related to limitation of liability.

[12] As set forth in Exchange Rule 11.2, ''[a]ll securities designated for trading are eligible for odd-lot, round-lot and mixed-lot executions, unless otherwise indicated by the Exchange or limited pursuant to [the Exchange's] Rules.''

[13] *See* Notice, *supra* note 3, for additional details on such technical changes.

[14] *See* Rule 11.11(a).

of the TIRs on the Exchange. Trading of the TIRs on the Exchange will be subject to the Exchange's surveillance procedures for derivative products. The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. The Exchange provides that it prohibits the distribution of material, non-public information by its employees.

Suitability

Currently, BATS Rule 3.7 governs Recommendations to Customers, and Chapter III generally governs Rules of Fair Practice. Prior to the commencement of trading of any TIRs, the Exchange represents that it will remind its Members of the suitability requirements of BATS Rule 3.7 in an Information Circular.

FINRA has implemented increased sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged, and inverse leveraged securities and options on such securities, as described in FINRA Regulatory Notices 09–31 (June 2009), 09–53 (August 2009) and 09–65 (November 2009) (together, ''FINRA Regulatory Notices''). The Exchange provides that its Members that carry customer accounts will be required to follow the FINRA guidance set forth in the FINRA Regulatory Notices. The Information Circular will reference the FINRA Regulatory Notices regarding sales practice and customer margin requirements for FINRA members applicable to inverse, leveraged, and inverse leveraged securities and options on such securities.

The Exchange notes that, for inverse, leveraged, and inverse leveraged securities, the corresponding funds seek leveraged, inverse, or leveraged inverse returns on a daily basis, and do not seek to achieve their stated investment objective over a period of time greater than one day because compounding prevents the funds from perfectly achieving such results. Accordingly, results over periods of time greater than one day typically will not be a leveraged multiple (+200%), the inverse (−100%) or a leveraged inverse multiple (−200%) of the period return of the applicable benchmark and may differ significantly from these multiples. The Exchange's Information Circular, as well as the applicable registration statement, will provide information regarding the suitability of an investment in such securities.

Description of the Shares and the Funds

The Funds will seek to provide investment results (before fees and expenses) that correspond to the performance of the S&P Dynamic Futures Index (''DFI'' or ''Index'') or to a sub-index of the Index (''Sub-Index''). The ProShares Managed Futures Strategy will seek to provide investment results (before fees and expenses) that correspond to the performance of the DFI. The ProShares Commodity Managed Futures Strategy will seek to provide investment results (before fees and expenses) that correspond to the performance of the S&P Dynamic Commodities Futures Index (''DCFI''), a Sub-Index of the DFI. The ProShares Financial Managed Futures Strategy will seek to provide investment results (before fees and expenses) that correspond to the performance of the S&P Dynamic Financial Futures Index (''DFFI''), another Sub-Index of the DFI.

As mentioned above, the Commission has previously approved the listing and trading of the Funds on NYSE Arca.[15] Since approving the listing and trading of the Funds on NYSE Arca, the structure of the Index and its Sub-Indexes have not changed, and the underlying components remain the same. However, how the Index is administered has changed in the following manner:

- Rebalancing and positioning now occur on a component by component basis, rather than by sector.
- Energy components can now be held in long or short positions, rather than just long or flat (as further described herein).[16]
- Components are set to their annual weights on a monthly basis, as opposed to the previous sector structure in which the component weights floated throughout the year within the sector weights, which were reset monthly. Other than the foregoing, no other aspect of the Index or Sub-Indexes is changing.

The Index and each Sub-Index were developed by Standard & Poor's and are long/short rules-based investable indexes designed to capture the economic benefit derived from both rising and declining trends in futures prices.[17] The Index is composed of unleveraged positions in U.S. exchange-traded futures contracts on sixteen different tangible commodities (''Commodity Futures Contracts''), as well as U.S. exchange-traded futures contracts on eight different financials, such as major currencies and U.S. Treasury securities (''Financial Futures Contracts'' and together with the Commodity Futures Contracts, ''Index Components'').[18] Commodity Futures Contracts and Financial Futures Contracts each comprise a Sub-Index of the Index: the DCFI and the DFFI, respectively (together, ''Sub-Indexes'').

Previously, the Index and the DCFI were designed such that the energy components would only be set long or flat (*i.e.,* zero weight), rather than long or short. The rationale for this was the heightened potential for significant losses in the event of a supply disruption of certain energy markets. The Index and the DCFI have been redesigned to allow energy components to be set long or short. The primary considerations in this determination were:

- Potential losses are mitigated by the limited weight attributable to any single energy component.
- The magnitude of energy market price movements during previous major market supply disruptions (*e.g.,* the Gulf Wars) does not support restricting short energy positions.

In order to achieve the investment objective of the Funds, the Sponsor will invest in: (i) Exchange-traded futures contracts of the type comprising the Index or Sub-Indexes, as applicable (''Futures Contracts'');[19] and/or (ii) under limited circumstances (as further described herein), swap agreements whose value is derived from the level of the Index, a Sub-Index, one or more Index Components, or, in the case of currency-based Financial Futures Contracts, the exchange rates underlying such Financial Futures Contracts, or invest in other futures contracts or swaps if such instruments tend to exhibit trading prices or returns that correlate with the Index or Sub-Indexes or any Index Component and will further the investment objective of the Fund. Each Fund may also invest in cash or cash equivalents such as U.S. Treasury securities or other high credit quality short-term fixed-income or similar securities (including shares of money market funds, bank deposits,

[15] *See supra* note 7.

[16] As previously approved, all sectors other than energy could go long and short.

[17] Standard & Poor's is not a broker-dealer, is not affiliated with a broker-dealer, and has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Index and Sub-Indexes.

[18] The Index Components are traded on the Chicago Mercantile Exchange, Inc. (''CME''), COMEX (a division of CME), Chicago Board of Trade (''CBOT,'' a division of CME), NYMEX (a division of CME), and ICE Futures US (''ICE'') (collectively, ''Futures Exchanges'').

[19] Futures Contracts will be the same type of contracts as the Index Components, but the expiration dates of such Futures Contracts may differ from the expiration dates of the Index Components at any given point in time.

bank money market accounts, certain variable rate-demand notes, and repurchase agreements collateralized by government securities) for direct investment or as collateral for the Futures Contracts or swap agreements. The Sponsor does not expect that the Funds will invest directly in any commodity or currency.

Each Fund will seek to achieve its investment objective by investing, under normal market circumstances,[20] in exchange-traded Futures Contracts. In the event position accountability rules or position limits with respect to a Futures Contract are reached with respect to a Fund, the Sponsor may, in its commercially reasonable judgment, cause such Fund to obtain exposure through swaps whose value is derived from the level of the Index, a Sub-Index, one or more Index Components, or, in the case of currency-based Financial Futures Contracts, the exchange rates underlying such Financial Futures Contracts, or invest in other futures contracts or swaps if such instruments tend to exhibit trading prices or returns that correlate with the Index, the Sub-Indexes, or any Index Component and will further the investment objective of the Funds.[21] The Funds may also invest in swaps if the market for a specific Futures Contract experiences emergencies (*e.g.,* natural disaster, terrorist attack, or an act of God) or disruptions (*e.g.,* a trading halt or a flash crash) that would prevent the Funds from obtaining the appropriate amount of investment exposure to the affected Futures Contracts or other futures contracts directly.[22]

The Index and the Sub-Indexes

The Index is composed of the Index Components, representing unleveraged long or short positions in U.S. exchange-traded futures contracts in the commodity and financial markets.[23] Index Components are chosen based on fundamental characteristics and liquidity. The Commodity Futures Contracts comprise the DCFI as described below, and the Financial Futures Contracts comprise the DFFI, as described below.

Weightings of the Commodity Futures Contracts are based on generally known world production levels, as adjusted to limit the impact of the energy-related Index Components. Weightings of the Financial Futures Contracts are based on, but not directly proportional to, gross domestic product (''GDP'').[24]

The positions the Index (and accordingly, each Sub-Index) takes in the Index Components are not long-only, but are set by component long or short, based on the relation of the current price input of each Index Component with a seven-month weighted moving average of the price inputs of the same Index Component.

Determining the Long/Short Positioning of the Index Components

The rules for the Index and each Sub-Index regarding long or short positions are summarized as follows:

- Long positions are tracked when an Index Component's current one-month price change is greater than or equal to the exponential weighted average of the past seven monthly price inputs.
- Short positions are tracked when an Index Component's current one-month price change is less than the exponential weighted average of the past seven monthly price inputs.

Monthly long or short positions are determined on the second to last DFI business day of the month (defined as the position determination date, or PDD) when the monthly percentage change of an Index Component's price is compared to past monthly price changes, exponentially weighted to give greatest weight to the most recent return and least weight to the return seven months prior.[25] The weighted sum of the percentage changes of all Index Component prices equals the daily movement of the Index.

Index Component Rebalancing

Index Component weights are fixed each year and rebalanced back to their annual base weight monthly. During this monthly rebalancing, the Index will also ''roll'' certain of its positions from the current contract to a contract further from settlement.[26]

Additional details regarding the Trust, Funds, Shares, trading policies and investment strategies of the Funds, creations and redemption procedures, fees, investment risks, Index and Sub-Indexes, NAV calculation, the dissemination and availability of information about the underlying assets, trading halts, applicable trading rules, surveillance, and the Information Bulletin, among other things, can be found in the Notice and/or the Registration Statement, as applicable.[27]

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act[28] and the rules and regulations thereunder applicable to a national securities exchange.[29] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[30] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Proposed Changes to Rule 14.11

The Commission finds the proposal to align Rule 14.11 to the rules of AMEX and NYSE Arca (including the related non-substantive, conforming, and

[20] The term ''under normal market circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the futures markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[21] To the extent practicable, the Funds will invest in swaps cleared through the facilities of a centralized clearing house.

[22] The Sponsor will also attempt to mitigate the Funds' credit risk by transacting only with large, well-capitalized institutions using measures designed to determine the creditworthiness of a counterparty. The Sponsor will take various steps to limit counterparty credit risk, as described in the Registration Statement.

[23] As set forth in the Index weighting scheme example below, the commodity portion of the Index consists of multiple commodities (*e.g.,* Energy, Industrial Metals) and each commodity is assigned a percentage weight. Similarly, the financial markets portion of the Index consists of multiple foreign currency and U.S. Treasury sectors (*e.g.,* Australian dollar, U.S. Treasury Notes), each with an assigned component weight.

[24] For initial 2012 weighting schemes for the Index and each Sub-Index and information about the exchange and trading hours for each Futures Contract, *see* Notice, *supra* note 3.

[25] *See* Notice, *supra* note 3, for more information about how an exponential average is created for comparison purposes.

[26] The Index is composed of Index Components, which are futures contracts. In order to maintain consistent exposure to the Index Components, each Index Component contract must be sold prior to its expiration date and replaced by a contract maturing at a specified date in the future. This process is known as rolling. Index Component contracts are rolled periodically. The rolls are implemented pursuant to a roll schedule over a five-day period from the first through the fifth Index business days of the month. An Index business day is any day on which the majority of the Index Components are open for official trading and official settlement prices are provided, excluding holidays and weekends.

[27] *See* Notice and Registration Statement, *supra* notes 3 and 6, respectively.

[28] 15 U.S.C. 78f.

[29] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78f(b)(5).

technical changes) consistent with Sections 6(b)(5) of the Act. As discussed above, the proposed changes to Rule 14.11 and the proposed adoption of Rule 14.11(f) would conform to similar standards for the listing and trading of TIRs on AMEX and NYSE Arca. The Commission notes that the listing requirements as proposed would be at least as stringent as those of AMEX and NYSE Arca. In addition, the proposed rule change is based on representations governing suitability, surveillance, the issuance of Information Circulars, and circumstances pursuant to which trading should be halted, among more general trading rules governing TIRs. The Commission believes these aspects of the proposal present no novel issues or significant regulatory concerns. The proposed rules should enhance competition in the marketplace to the benefit of investors.

Listing and Trading of the Shares

The Commission finds that the aspect of the proposal to list and trade the Shares on the Exchange is also consistent with Section 11A(a)(1)(C)(iii) of the Act,[31] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities.

The Commission notes that the Funds and the Shares must comply with the requirements of proposed BATS Rule 14.11(f) to be listed and traded on the Exchange. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line.

The IIV, which reflects a current estimated intraday value of Futures Contracts and other applicable holdings, cash, and receivables, less liabilities of each Fund, will be widely disseminated on a per Share basis by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Trading Hours.[32] The IIV will be updated during Regular Trading Hours when applicable Futures Exchanges are trading any Futures Contracts held by the Funds. However, the IIV that will be disseminated between 11:50 a.m. E.T. and the end of Regular Trading Hours will be impacted by static values for certain Futures Contracts.[33] For each Fund, the IIV will be calculated throughout Regular Trading Hours, using the prior day's closing NAV of such Fund as a base, and updated throughout the trading day as each Fund's Futures Contracts, cash equivalents, swap agreements, if applicable, and other applicable holdings change in value.

Each Fund's total portfolio composition will be disclosed on such Fund's Web site or another relevant Web site as determined by the Trust and/or the Exchange. The Trust will provide Web site disclosure of portfolio holdings daily and will include, as applicable, the names, notional value (in U.S. dollars) and number of Futures Contracts or units of swaps held by a Fund, if any, cash equivalents, and the amount of cash held in the portfolio of each Fund. This public Web site disclosure of the portfolio composition of the Funds will occur at the same time as the disclosure by the Sponsor of the portfolio composition to authorized participants, so that all market participants are provided portfolio composition information at the same time.

The NAV for the Funds will be calculated daily by the Administrator at 3:00 p.m. E.T. and will be disseminated daily to market participants. Additionally, the Exchange will make available on its Web site daily trading volume of the Shares. Daily trading volume information will also be available in the financial section of newspapers, their related Web sites or other financial Web sites, through subscription services, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public Web sites.

The intraday, closing, and settlement prices of the Futures Contracts are also readily available, as applicable, from the respective Futures Exchanges. The Web site for the Funds will include a form of the prospectus for the Funds, additional data relating to NAV, and other applicable quantitative information. The daily closing Index level and the percentage change in the daily closing Index level for the Index and each Sub-Index will be publicly available from one or more major market data vendors. Data regarding the Index and each Sub-Index, updated every 15 seconds during Regular Trading Hours, is also available from Standard & Poor's on a subscription basis. Several independent data vendors also package and disseminate Index and Sub-Index data in various value-added formats (including vendors displaying both Index constituents and Index levels and vendors displaying Index levels only). Data regarding the Index Components is also available from the Web sites of the Futures Exchanges. Data regarding the commodities, currencies, and Treasury securities underlying the Index Components is publicly available from various financial information service providers.

The Commission believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation (prior to listing of Shares of each Fund) from the Trust that the NAV per Share will be calculated daily and made available to all market participants at the same time. In addition, if the Exchange becomes aware that the NAV with respect to a series of the TIRs is not disseminated to all market participants at the same time, it will halt trading in such series until such time as the NAV is available to all market participants.[34] Trading in the Shares will also be subject to BATS Rule 11.18, which sets forth circumstances under which Shares of the Funds may be halted.[35] If any of the IIV, the level of the underlying index, or the value of the underlying assets of the TIRs is not being disseminated as required, the Exchange may halt trading during the day in which such interruption to the dissemination occurs. If an interruption to the dissemination of the IIV, the value of the underlying index, or the value of the underlying assets of the TIRs persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the

[31] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[32] According to the Exchange, several major market data vendors display and/or make widely available IIVs published via the CTA or other data feeds.

[33] The value of the IIV will be based on the underlying Futures Contracts. Once a particular Futures Contract settles, a static closing value for that Futures Contract will be used to calculate the IIV, which will continue to update based on any other futures contracts that have not reached their settlement time. The IIV should not be viewed as an actual real-time update of the NAV because NAV is calculated only once each trading day at 3:00 p.m. E.T. In addition, the IIV also should not be viewed as a precise value of the Shares.

[34] *See* Notice, *supra* note 3.

[35] *See* BATS Rule 11.18. The Exchange further represents that trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the futures contracts and/or the financial instruments comprising the Funds; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.

interruption.[36] Further, the Commission notes that the Exchange states that it prohibits the distribution of material, non-public information by its employees.[37] Finally, with respect to the Index and Sub-Indexes, Standard & Poor's is not a broker-dealer, is not affiliated with a broker-dealer, and has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Index and Sub-Indexes.

The Exchange further represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) For initial and/or continued listing of the Shares, the Funds must be in compliance with Exchange Rule 14.11(f) and Rule 10A–3 under the Act.[38]

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures applicable to derivative products, which include TIRs, are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange is able to obtain information via the ISG from other exchanges that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[39] In addition, for components traded on exchanges, not more than 10% of the weight of a Fund's portfolio in the aggregate shall consist of components whose principal trading market is not a member of ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. All Futures Contracts will be traded on a trading market that is a member of ISG or is a market with which the Exchange has a comprehensive surveillance sharing agreement.

(4) Prior to the commencement of trading of the Shares, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, BATS Rule 3.7 provides that, in recommending transactions in the Shares, a Member must have reasonable grounds for believing that (a) the recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such Member, and (b) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in the securities. In connection with the suitability obligation, the Circular will also provide that Members must make reasonable efforts to obtain the following information: (a) The customer's other securities holdings; (b) the customer's financial situation and needs; (c) the customer's investment objectives; and (d) such other information used or considered to be reasonable by such Member or registered representative in making recommendations to the customer.

(5) Each Fund will seek to achieve its investment objective by investing, under normal market circumstances, in exchange-traded Futures Contracts. In the event position accountability rules or position limits with respect to a Futures Contract are reached with respect to a Fund, the Sponsor may, in its commercially reasonable judgment, cause such Fund to obtain exposure through swaps whose value is derived from the level of the Index, a Sub-Index, one or more Index Components, or, in the case of currency-based Financial Futures Contracts, the exchange rates underlying such Financial Futures Contracts or invest in other futures contracts or swaps if such instruments tend to exhibit trading prices or returns that correlate with the Index, the Sub-Indexes, or any Index Component and will further the investment objective of the Funds. The Funds may also invest in swaps if the market for a specific Futures Contract experiences emergencies (*e.g.,* natural disaster, terrorist attack, or an act of God) or disruptions (*e.g.,* a trading halt or a flash crash) that would prevent the Funds from obtaining the appropriate amount of investment exposure to the affected Futures Contracts or other futures contracts directly.

(6) To the extent practicable, the Funds will invest in swaps cleared through the facilities of a centralized clearing house. In addition, the Sponsor will also attempt to mitigate the Funds' credit risk by transacting only with large, well-capitalized institutions using measures designed to determine the creditworthiness of a counterparty. The Sponsor will take various steps to limit counterparty credit risk, as described in the Registration Statement.

(7) The anticipated minimum number of Shares for each Fund to be outstanding at the start of trading will be 100,000 Shares.

(8) The NAV per Share will be calculated daily and made available to all market participants at the same time.

This approval order is based on all of the Exchange's representations and description of the Funds, including those set forth above and in the Notice.[40]

For the foregoing reasons, the Commission finds that the proposed rule change to amend Rule 14.11 and to list and trade the Shares pursuant to Rule 14.11, as proposed to be amended, is consistent with Sections 6(b)(5) of the Act[41] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[42] that the proposed rule change (SR–BATS–2012–044) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–00796 Filed 1–15–13; 8:45 am]

BILLING CODE 8011–01–P

[36] *See* BATS Rule 14.11(f)(4)(C)(ii) (providing additional considerations for the removal from listing of TIRs on the Exchange).

[37] *See* Notice, *supra* note 3.

[38] *See* 17 CFR 240.10A–3.

[39] *See* Notice, *supra* note 3.

[40] The Commission notes that it does not regulate the market for futures in which the Fund plans to take positions, which is the responsibility of the Commodity Futures Trading Commission (''CFTC''). The CFTC has the authority to set limits on the positions that any person may take in futures. These limits may be directly set by the CFTC or by the markets on which the futures are traded. The Commission has no role in establishing position limits on futures even though such limits could impact an exchange-traded product that is under the jurisdiction of the Commission.

[41] 15 U.S.C. 78f(b)(5).

[42] 15 U.S.C. 78s(b)(2).

[43] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13439 and #13440]

Mississippi Disaster #MS–00063

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Mississippi dated 01/04/2013.

Incident: Severe storms and tornadoes.

Incident Period: 12/25/2012.

DATES: *Effective Date:* 01/04/2013.

Physical Loan Application Deadline Date: 03/05/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 10/04/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Pearl River.

Contiguous Counties:

Mississippi; Forrest, Hancock, Harrison, Lamar, Marion, Stone.

Louisiana; Saint Tammany, Washington.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.500
Homeowners Without Credit Available Elsewhere	1.750
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13439 C and for economic injury is 13440 0.

The States which received an EIDL Declaration # are Mississippi, Louisiana.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 4, 2013.

Karen G. Mills,

Administrator.

[FR Doc. 2013–00780 Filed 1–15–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13437 and #13438]

Puerto Rico Disaster #PR–00017

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the Commonwealth of Puerto Rico Dated 01/03/2013.

Incident: Heavy rains and flooding.

Incident Period: 11/12/2012 through 11/13/2012.

Effective Date: 01/03/2013.

Physical Loan Application Deadline Date: 03/04/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 10/03/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Municipality: Vega Baja.

Contiguous Municipalities: Manati, Morovis, Vega Alta.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.375
Homeowners Without Credit Available Elsewhere	1.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	3.125
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 134376 and for economic injury is 134380.

The Commonwealth which received an EIDL Declaration # is Puerto Rico.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: January 3, 2013.

Karen G. Mills,

Administrator.

[FR Doc. 2013–00484 Filed 1–15–13; 8:45 am]

BILLING CODE 8025–01–M

SMALL BUSINESS ADMINISTRATION

Claritas Capital Specialty Debt II, L.P.; Application No. 99000779; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Claritas Capital Specialty Debt II, L.P., 30 Burton Hills Blvd., Suite 100, Nashville, TN 37215, a Federal Licensee applicant under the Small Business Investment Act of 1958, as amended (the ''Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Claritas Capital Specialty Debt II, L.P. proposes to invest in Employment Control Holding Company, LLC, a portfolio company of its Associate Claritas Capital Specialty Debt Fund, L.P.

The financing is brought within the purview of § 107.730(a) of the Regulations because Claritas Capital Specialty Debt II, L.P. proposes to Finance a small business in which its Associate Claritas Capital Specialty Debt Fund, L.P. has an equity interest of at least 10 percent, so the transaction that will effect the proposed Financing requires prior SBA exemption.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: December 21, 2012.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2013–00799 Filed 1–15–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13394 and #13395]

Maryland Disaster Number MD–00025

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Maryland (FEMA–4091–DR), dated 11/20/2012.

Incident: Hurricane Sandy.

Incident Period: 10/26/2012 through 11/04/2012.

Effective Date: 01/03/2013.

Physical Loan Application Deadline Date: 01/21/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 08/20/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Maryland, dated 11/20/2012, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Baltimore.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–00485 Filed 1–15–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small business Investment Company License No. 09/79–0413 issued to Capstone Venture Partners SBIC, LP, and said license is hereby declared null and void.

United States Small Business Administration.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2013–00782 Filed 1–15–13; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small business Investment Company License No. 02/72–0592 issued to Madison Investment Partners II, L.P., and said license is hereby declared null and void.

United States Small Business Administration.

Dated: August 23, 2012.

Sean J. Greene,

Associate Administrator for Investment.

[FR Doc. 2013–00785 Filed 1–15–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 8154]

The Designation of Michel Samaha, AKA Saadah al-Naib Mishal Fuad Samahah, AKA Mishal Fuad Samahah, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Michel Samaha, AKA Saadah al-Naib Mishal Fuad Samahah, AKA Mishal Fuad Samahah committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in Section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 8, 2013.

William J. Burns,

Deputy Secretary of State.

[FR Doc. 2013–00828 Filed 1–15–13; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2012–0179]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under the procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 18, 2013.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2011–0129 using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, 1200 New Jersey Ave. SE., Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through

Friday, except Federal holidays. Fax: 1–202–493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without changes to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Julie Kang, Ph.D., Contracting Officer's Technical Representative Task Order Manager, Office of Human-Vehicle Performance Research (NVS–331), National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590. Dr. Kang's phone number is 202–366–7664. Her email address is *julie.kang@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Driver Monitoring of Inattention and Impairment Using Vehicle Equipment (Phase 2)

Type of Request—New information collection requirement.

OMB Clearance Number—None.

Form Number—NHTSA Form 1157.

Requested Expiration Date of Approval—Two years from date of approval.

Summary of the Collection of Information—NHTSA proposes to collect information from the public as part of a multipart study to develop and evaluate vehicle-based algorithms to detect and mitigate impairment and inattention. Questions will be asked in conjunction with a pair of simulator experiments to determine eligibility, and to provide details about the individuals and their experiences in the simulator that are necessary to explain the simulator data.

Description of the Need for the Information and Proposed Use of the Information—The National Highway Traffic Safety Administration's (NHTSA) mission is to save lives, prevent injuries, and reduce healthcare and other economic costs associated with motor vehicle crashes. In 2010, 899,000 police-reported crashes involved a distracted driver. This number accounts for 17 percent of the total number of police-reported crashes. Driver distraction is the diversion of attention from activities critical for safe driving to a competing activity. Examples of these tasks include talking on a cell phone, reaching for an object, or using a digital music player. NHTSA estimates that 100,000 police-reported crashes each year are the result of driver fatigue, but this estimate may be conservative. There are no tests to accurately determine fatigue and it is a difficult driver state to measure.

In a continuing effort to reduce the adverse consequences of impaired and inattentive driving, NHTSA in conjunction with the National Advanced Driving Simulator (NADS) is undertaking research to develop and evaluate vehicle-based algorithms that will detect impaired driving, e.g. driving while intoxicated, distracted, or drowsy. The agency believes that use of vehicle-based, detection technologies could help to significantly reduce the number of impaired driving crashes by alerting drivers to stop driving or disengage with distracting activities.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—Under this proposed effort, the Contractor will contact approximately 168 individuals for the phone-screening portion of the study. The screening is roughly 10 minutes in length. It is estimated that 100 of these individuals will be enrolled into the study to obtain the 72 completed data sets. The individuals contacted are persons in Eastern Iowa who have volunteered to take part in a driving simulation study. Businesses are ineligible for the sample and will not be contacted.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting From the Collection of Information—It is estimated that the total respondent burden will be 203 hours. There are two experiments: Track A and Track B. Individuals in Track A will have a burden of 30–45 minutes and individuals in Track B will have a burden of 150–180 minutes. Respondents who only complete the phone screening will have a burden of 10 minutes. The respondents will not incur any reporting cost from the information collection. The respondents also will not incur any recordkeeping burden or recordkeeping cost from the information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Joseph Carra,

Acting Associate Administrator, Office of Vehicle Safety Research.

[FR Doc. 2013–00798 Filed 1–15–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35711]

KM Railways, LLC—Acquisition and Operation Exemption—DTE Chicago Fuels Terminal, LLC and DTE Coal Services, Inc.

KM Railways, LLC (KMR), a Class III rail carrier,[1] has filed a verified notice of exemption under 49 CFR 1150.41 to acquire from DTE Chicago Fuels Terminal, LLC (DTE Chicago), and DTE Coal Services, Inc. (DTE Coal), both noncarriers,[2] and to operate 9,350 feet of rail line, which connects with a line of Norfolk Southern Railway Company in Chicago, Cook County, Ill.[3]

The transaction may be consummated on or after January 30, 2013 (30 days after the notice of exemption was filed).

[1] KMR is indirectly owned by noncarrier Koch Industries, Inc. (Koch). In addition to KMR, Koch also controls directly or indirectly three other Class III rail carriers (Old Augusta Railroad, LLC, Blue Rapids Railway Company, LLC, and Moscow, Camden and San Augustine Railroad, LLC), and Koch has sought Board authority to control a fourth Class III rail carrier (Texas South-Eastern Railroad Company). *See Koch Indus.—Acq. of Control Exemption—Tex. S. R.R.,* FD 35708 (STB served Jan. 11, 2013).

[2] On December 20, 2012, KMR, together with an affiliated Koch-owned entity, KCBX Terminals Company, entered into an Asset Purchase Agreement with DTE Chicago and DTE Coal. Under the terms of the agreement, KMR acquired the above-specified trackage and related rail facilities.

[3] KMR states there are no designated mileposts.

KMR certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.[4]

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than January 23, 2013 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35711, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on David H. Coburn, 1330 Connecticut Ave. NW., Washington, DC 20036.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: January 11, 2013.

By the Board, Richard Armstrong, Acting Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2013–00831 Filed 1–15–13; 8:45 am]

BILLING CODE 4915–01–P

[4] By letter filed on January 8, 2013, KMR supplemented the notice of exemption, advising the Board that KMR's projected annual revenues will not exceed $5 million.

DEPARTMENT OF THE TREASURY

Departmental Offices

Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 2, § 10(a)(2), that a meeting will be held at the Hay-Adams Hotel, 16th Street and Pennsylvania Avenue, NW.,Washington, DC, on February 5, 2013 at 11:30 a.m. of the following debt management advisory committee:

Treasury Borrowing Advisory Committee of The Securities Industry and Financial Markets Association.

The agenda for the meeting provides for a charge by the Secretary of the Treasury or his designate that the Committee discuss particular issues and conduct a working session. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. App. 2, § 10(d) and Public Law 103–202, § 202(c)(1)(B)(31 U.S.C. 3121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. App. 2, § 10(d) and vested in me by Treasury Department Order No. 101–05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103–202, § 202(c)(1)(B).

Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B). In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 2, § 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the Committee, premature disclosure of the Committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

Treasury staff will provide a technical briefing to the press on the day before the Committee meeting, following the release of a statement of economic conditions and financing estimates. This briefing will give the press an opportunity to ask questions about financing projections. The day after the Committee meeting, Treasury will release the minutes of the meeting, any charts that were discussed at the meeting, and the Committee's report to the Secretary.

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency official who may be contacted for additional information is Fred Pietrangeli, Deputy Director for Office of Debt Management (202) 622–1876.

Dated: January 8, 2013.

Matthew S. Rutherford,

Assistant Secretary, Financial Markets.

[FR Doc. 2013–00595 Filed 1–15–13; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 14417–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 14417–A, Statistics of Income—User Fee.

DATES: Written comments should be received on or before March 18, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 622–3634, at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Statistics of Income—User Fee.

OMB Number: 1545–2235.

Form Number: 14417–A.

Abstract: Form 14417–A, Statistics of Income—User Fee, was developed to be used after a customer contacts the Statistics of Income (SOI) Division requesting data not already available on our TaxStats IRS Web site.

Current Actions: This is a new form. We are requesting that this form be added under the 1545–2235 approval number.

Type of Review: Revision of a currently approved collection.

Affected Public: State, Local, and Tribal Governments.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 10.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 9, 2013.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. 2013–00747 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request on Information Collection Tools Relating to Customer Satisfaction Surveys

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing Customer Satisfaction Surveys previously approved under OMB approval number 1545–1432.

DATES: Written comments should be received on or before March 18, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3634, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION: Currently, the IRS is seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: IRS Customer Satisfaction Surveys.

OMB Number: 1545–NEW.

Form Number: N/A.

Abstract: We are requesting a three-year approval to conduct 41 specific customer satisfaction and opinion surveys, which will allow the Agency to continue to use a data-driven approach to understanding customer satisfaction at the Internal Revenue Service (IRS). Collecting, analyzing, and using customer opinion data is a vital component of IRS's Balanced Measures Approach, as mandated by Internal Revenue Service Reform and Restructuring Act of 1998 and Executive Order 12862.

Current Actions: This is a new request for OMB approval.

Type of Review: New collection.

Affected Public: The information collected from taxpayers, practitioners, and a few small entities, will help ensure that users of IRS programs and services have an effective, efficient, and satisfying experience. In regard to online services, this feedback will provide insights into customer preferences for online information and services on IRS.gov that will meet their needs to resolve inquiries and their accounts on their own. This collection of feedback will contribute directly to the improvement of content and services provided online.

Estimated Number of Respondents: 1,000,000.

Estimated Time per Respondent: 10 min.

Estimated Total Annual Burden Hours: 150,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 9, 2013.

R. Joseph Durbala,

IRS Reports Clearance Officer.

[FR Doc. 2013–00746 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, February 12, 2013.

FOR FURTHER INFORMATION CONTACT: Donna Powers at 1–888–912–1227 or 954–423–7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Tuesday, February 12, 2013, at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Donna Powers. For more information please contact Ms. Powers at 1–888–912–1227 or 954–423–7977, or write TAP Office, 1000 South Pine Island Road, Suite 340, Plantation, FL 33324, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various IRS Issues.

Dated: January 10, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00753 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee.

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, February 19, 2013.

FOR FURTHER INFORMATION CONTACT: Marianne Dominguez at 1–888–912–1227 or 954–423–7978.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Tuesday, February 19, 2013 at 11:00 a.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Marianne Dominguez. For more information please contact Ms. Dominguez at 1–888–912–1227 or 954–423–7978, or write TAP Office, 1000 South Pine Island Road, Suite 340, Plantation, FL 33324, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various IRS issues.

Dated: January 10, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00752 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, February 13, 2013.

FOR FURTHER INFORMATION CONTACT: Timothy Shepard at 1–888–912–1227 or 206–220–6095.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Wednesday, February 13, 2013, at 12 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Timothy Shepard. For more information please contact Mr. Shepard at 1–888–912–1227 or 206–220–6095, or write TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various IRS Issues.

Dated: January 10, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00745 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, February 27, 2013.

FOR FURTHER INFORMATION CONTACT: Susan Gilbert at 1–888–912–1227 or (515) 564–6638.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, February 27, 2013 at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Susan Gilbert. For more information please contact Ms. Gilbert at 1–888–912–1227 or (515) 564–6638 or write: TAP Office, 210 Walnut Street, Stop 5115, Des Moines, IA 50309 or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various IRS topics.

Dated: January 10, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00751 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee.

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, February 13, 2013.

FOR FURTHER INFORMATION CONTACT: Marisa Knispel at 1–888–912–1227 or 718–488–3557.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be held Wednesday, February 13, 2013 at 11:00 a.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Ms. Knispel. For more information please contact Ms. Knispel at 1–888–912–1227 or 718–488–3557, or write TAP Office, 10 MetroTech Center, 625 Fulton Street, Brooklyn, NY 11201, or post comments to the Web site: *http://www.improveirs.org.*

The agenda will include various IRS issues.

Dated: January 10 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00750 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, February 21, 2013.

FOR FURTHER INFORMATION CONTACT: Ellen Smiley or Patti Robb at 1–888–912–1227 or 414–231–2360.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, February 21, 2013 at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Ms. Ellen Smiley. For more information please contact Ms. Smiley at 1–888–912–1227 or 414–231–2360, or write TAP Office Stop 1006MIL, 211 West Wisconsin Avenue, Milwaukee, WI 53203–2221, or post comments to the Web site: *http://www.improveirs.org.*

The agenda will include various IRS issues.

Dated: January 10, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–00754 Filed 1–15–13; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 78 Wednesday,

No. 11 January 16, 2013

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1, 16, 106, Et al.

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA) is proposing to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is proposing these standards as part of our implementation of the FDA Food Safety Modernization Act (FSMA). These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect that the proposed rule, if finalized as proposed, would reduce foodborne illness associated with the consumption of contaminated produce.

DATES: Submit either electronic or written comments on the proposed rule by May 16, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 15, 2013 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0921 and/or Regulatory Information Number RIN 0910–AG35, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0921 and Regulatory Information Number RIN 0910–AG35 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
Proposed Rule
I. Introduction
  A. Contamination With Microbiological Hazards
  B. Contamination With Chemical, Physical or Radiological Hazards
II. Efforts To Address Produce Safety
  A. Inspections and Investigations
  B. Guidance Documents and Letters to Industry
  C. Produce Safety Action Plan
  D. Public Hearings
  E. Partnerships and Collaborations
  F. Current Industry Practices
  G. 2010 Federal Register Notice and Preliminary Stakeholder Comments
  H. White House Food Safety Working Group
  I. Other Related Issues
III. Legal Authority
  A. Section 105 of FSMA and Section 419 of the FD&C Act
  B. Other Provisions of the FD&C Act
  C. The Public Health Service Act
  D. Legal Authority for Records Requirements
  E. Intrastate Activities
  F. Relevance of Section 415 of the FD&C Act to ''Farm'' Definition and Related Definitions
IV. Regulatory Approach
  A. Qualitative Assessment of Risk
  B. Focus on Biological Hazards
  C. Consideration of Differing Risk of Different Commodities and Practices
  D. Framework of the Rule
  E. Records
  F. Farm-specific Food Safety Plans
  G. Foreign Farms
  H. Consistency With Codex Guidelines
  I. Product Testing as a Strategy to Control Pathogens
  J. Effective Dates
  K. Compliance Dates
V. The Proposal
  A. Subpart A—General Provisions
  B. Subpart B—General Requirements
  C. Subpart C—Standards Directed to Personnel Qualifications and Training
  D. Subpart D—Standards Directed to Health and Hygiene
  E. Subpart E—Standards Directed to Agricultural Water
  F. Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste
  G. Reserved
  H. Reserved
  I. Subpart I—Standards Directed to Domesticated and Wild Animals
  J. Reserved
  K. Subpart K—Standards Directed to Growing, Harvesting, Packing and Holding Activities
  L. Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation
  M. Subpart M—Standards Directed to Sprouts
  N. Subpart N—Analytical Methods
  O. Subpart O—Requirements Applying to Records That You Must Establish and Keep
  P. Subpart P—Variances
  Q. Subpart Q—Compliance and Enforcement
  R. Subpart R—Withdrawal of Qualified Exemption
VI. Preliminary Regulatory Impact Analysis
VII. Analysis Of Environmental Impact
VIII. Federalism
IX. Comments
X. References

Executive Summary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) requires FDA to publish a notice of proposed rulemaking to establish science-based

minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of serious adverse health consequences or death. Further, new section 419 also requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

This proposed rule focuses on microbiological hazards related to produce growing, harvesting, packing, and holding. We conducted a ''Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce'' and considered the findings of this assessment in developing this proposed rule. While we acknowledge the potential for chemical, physical or radiological contamination of produce, for reasons discussed in this proposed rule, we are not proposing specific standards for these hazards in this rulemaking.

Scope of Coverage of the Proposed Rule

The proposed rule would apply to both domestic and imported produce. However, as explained in the remainder of this document, the proposed rule contains several exemptions:

- The proposed rule would not apply to certain specified produce commodities that are rarely consumed raw.
- The proposed rule also would not apply to produce that is used for personal or on-farm consumption, or that is not a raw agricultural commodity.
- The proposed rule would provide an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms (*e.g.* a ''kill step'') as long as certain documentation is kept.
- The proposed rule would not cover farms that have an average annual value of food sold during the previous three-year period of $25,000 or less.
- The proposed rule would provide a qualified exemption and modified requirements for farms that meet two requirements: (1) The farm must have food sales averaging less than $500,000 per year during the last three years; and (2) the farm's sales to qualified end-users must exceed sales to others. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away. Instead, these farms would be required to include their name and complete business address either on the label of the produce that would otherwise be covered (if a label is required under the FD&C Act and its implementing regulations) or at the point-of-purchase. This exemption may be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions on the farm that are material to the safety of the produce. As explained in the Preamble, these entities are either exempt from all the requirements of the rule or are subject to a narrower set of requirements.

Summary of the Major Provisions of the Regulatory Action

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. We propose new standards in the following major areas:

- Worker Training and Heath and Hygiene
  - Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors (proposed §§ 112.21, 112.22, and 112.23);
  - Require documentation of required training (proposed § 112.30); and
  - Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance (proposed §§ 112.31, 112.32, and 112.33).
- Agricultural Water
  - Require that all agricultural water must be of safe and sanitary quality for its intended use (proposed § 112.41). Agricultural water is defined in part as water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces (proposed § 112.3(c));
  - Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce (proposed §§ 112.42 and 112.46);
  - Require treatment of agricultural water if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment (proposed § 112.43);
  - Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards (proposed §§ 112.44 and 112.45); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.50).
- Biological Soil Amendments
  - Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51, 112.52)
  - Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements (proposed § 112.53);
  - Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards (proposed §§ 112.54 and 112.55); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12);
  - Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56); and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and
  - Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60).

- Domesticated and Wild Animals
  - ○ If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, require, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (proposed § 112.82); and
  - ○ If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season (proposed § 112.83).
- Equipment, Tools, and Buildings
  - ○ Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta (proposed §§ 112.121–134); and
  - ○ Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities (proposed § 112.140).
- Sprouts
  - ○ Establish measures that must be taken related to seeds or beans for sprouting (proposed § 112.141);
  - ○ Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts (proposed § 112.142);
  - ○ Require that you test the growing environment for *Listeria* spp. or *L. monocytogenes* and that you test each production batch of spent irrigation water or sprouts for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions (proposed §§ 112.143, 112.144, 112.145, 112.146); and
  - ○ Require certain records, including documentation of your treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used (proposed § 112.150).

As proposed, the effective date is 60 days after a final rule is published, however, we are providing for a longer timeline for farms to come into compliance. Small businesses (*i.e.,* those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $500,000) would have three years after the effective date to comply; for some of the water requirements, they would have five years. In addition, very small businesses (*i.e.,* those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $250,000) would have four years after the effective date to comply; for some of the water requirements, they would have six years. All other farms would have two years after the effective date to comply; for some of the water requirements, they would have four years to comply.

Costs and Benefits

The baseline estimate for preventing all illnesses associated with microbial contamination of produce covered by this proposed regulation is $1.6 billion; however, we do not expect that we will eliminate all illnesses associated with covered produce. Instead, we expect that the proposed produce safety regulation will prevent some portion of this illness burden from recurring. We estimate the number of foodborne illness prevented by this regulation to be 1.75 million, with an associated benefit of $1.04 billion, annually. As described in the Preliminary Regulatory Impact Analysis (PRIA), making a precise estimate of the rule's likely effectiveness is extremely difficult, because FDA has only limited data that would establish a clear baseline estimate of how contamination occurs and the likely impact of the proposed provisions on that baseline, with respect to causing human illness. We estimate the costs of the proposed rule to be $459.56 million annually for domestic farms, $170.62 million annually for foreign farms covered by the rule (for a grand total of $630.18 million annually), resulting in $406.22 million annually in estimated potential net benefits.

Summary of Costs and Benefits of the Proposed Rule [1]	Prevented foodborne Illnesses (in millions)	Total benefits (in millions)	Total domestic costs (in millions)	Total foreign costs (in millions)	Total costs (domestic + foreign)	Net benefits (in millions)
Total	1.75	$1,036.40	$459.56	$170.62	$630.18	$406.22

	Very small	Small	Large
Average Annual Cost per Farm	$4,697	$12,972	$30,566

[1] As described in detail in the PRIA, data to estimate the costs and benefits of this rule are limited. Best estimates were made for both the costs and the benefits of the rule, given the data available. We request comment on these estimations, and request, in particular, data related to the amount of contamination attributable to each potential pathway of contamination, the relative effectiveness of each provision at reducing contamination, and data related to current industry food safety practices.

Proposed Rule

I. Introduction

Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to estimates from the Centers for Disease Control and Prevention. The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than primarily reacting to problems after they occur. The law also provides us with new enforcement authorities to help us achieve higher rates of compliance with prevention- and risk-based safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and directs us to build an integrated national food safety system in partnership with State and local authorities.

Section 105 of FSMA adds section 419 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350h) requiring FDA to publish a notice of proposed rulemaking to establish science-based minimum standards for

the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards are necessary to minimize the risk of serious adverse health consequences or death. Further, new section 419 also requires FDA to adopt a final regulation based on known safety risks, setting forth procedures, processes, and practices that we determine to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. This proposed rule sets forth such standards, as well as certain exemptions from the standards, consistent with section 419 of the FD&C Act.

Two additional proposed rules, with the produce safety proposed rule, will be the foundation of, and central framework for, a new food safety system in the United States. In an accompanying notice in this issue of the **Federal Register**, FDA is publishing the preventive controls proposed rule that would apply to human food and require domestic and foreign facilities that are required to register under the FD&C Act to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, monitor results, and act to correct problems that arise.

FDA also intends to publish the foreign supplier verification program (FSVP) proposed rule, which would help ensure the safety of foods imported into the U.S. by making importers accountable for verifying that the food they import is produced using processes and procedures that achieve the same level of public health protection for imported food as required of domestic growers and processors under FSMA's new standards for produce safety and preventive controls.

Eating fruits and vegetables is an important part of a healthy diet (Ref. 1). FDA is responsible for ensuring the safety of all domestic and imported fruits and vegetables consumed in the United States. We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with produce and maintain a high level of consumer confidence in this important food category. Produce is vulnerable to contamination with microorganisms of public health significance (*e.g.,* bacteria and viruses that can cause disease), as well as chemical, physical, and radiological contaminants. Contamination of produce can occur on-farm during growing (either in an open environment or in a fully- or partially-enclosed building), harvesting, packing, or holding; or elsewhere along the farm-to-table continuum.

A. Contamination With Microbiological Hazards

American consumers enjoy one of the safest supplies of produce in the world. Over the last few decades, however, problems linked to produce, including the associated public health implications, have been reported in a number of countries worldwide. Many factors affect the occurrence of microbial contamination of fresh produce, including worker health and hygiene, the quality of agricultural water, the use of animal manure and other materials of animal origin as fertilizer, the presence of wild or domestic animals in or near fields or packing areas, growing and harvesting operations, and equipment and building sanitation. As discussed in more detail below, FDA has taken several steps to help reduce the likelihood of microbial contamination; significant advances have been made. However, in spite of these efforts, produce-associated foodborne illnesses continue.

FDA has looked specifically at outbreaks where the point of contamination is likely to have happened early in the production chain, during growing, harvesting, manufacturing, processing, packing, holding, or transportation (Ref. 2). Of the total reported outbreaks and outbreak-related illnesses linked to FDA-regulated foods between 1996 and 2010, in the FDA database, produce accounted for 23.3% and 42.3%, respectively. Both domestic produce and imported produce were identified as vehicles in these outbreaks. From 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,132 outbreak-related illnesses, 1,360 hospitalizations and 27 deaths. These outbreaks were associated with approximately 20 different fresh produce commodities (Ref. 3). Commodities associated with outbreaks during this time period included sprouts; leafy greens such as lettuce and spinach; tomatoes; melons such as cantaloupe and honeydew; berries such as raspberries, blueberries, blackberries, and strawberries; fresh herbs such as basil and parsley; and green onions as well as fresh-cut fruits and vegetables. FDA also has evidence that contamination occurs on some produce crops at least intermittently based on sampling performed as part of investigation, inspections, and FDA Domestic and Import Field Assignments and data from United States Department of Agriculture (USDA)'s Agricultural Marketing Service (AMS) Microbiological Database program (MDP) (Ref. 4 Ref. 5). For instance, in 2009, AMS tested eight types of produce for E. coli O157:H7, non-O157 E. coli carrying shiga toxin and enterotoxin genes, and Salmonella. MDP identified 51 samples with E. coli carrying shiga toxin genes; however only 24 of these were determined to be pathogenic. MDP identified 32 samples with Salmonella confirmed by culture. The USDA AMS MDP was discontinued in 2012 and FDA is evaluating options for any future collection of similar microbiological data.

The following commodities accounted for 88.5% of the total produce-associated outbreaks:

- 34 outbreaks associated with sprouts,
- 30 outbreaks associated with leafy greens such as lettuce and spinach
- 17 outbreaks associated with tomatoes
- 14 outbreaks associated with melons such as cantaloupe and honeydew
- 10 outbreaks associated with berries, such as raspberries, blueberries, blackberries and strawberries
- 6 outbreaks associated with fresh herbs such as basil and parsley
- 3 outbreaks associated with green onions.

(Ref. 2)

In the FDA database, fresh-cut fruits and vegetables accounted for 16.8% of the total produce-related outbreaks. Generally, the most likely point of original contamination for the fresh-cut-related outbreaks, as determined by FDA and its federal and state partners during the outbreak investigations, appears to be during growing, harvest, packing or holding, while the commodity is still in its raw agricultural commodity (RAC) form, rather than during manufacturing/processing of the fresh-cut product (Ref. 2). In a few instances, such as unwashed, field packed tomatoes being removed from a warm ripening room and placed in cold water to firm for slicing (which may have promoted infiltration of pathogens) (Ref. 6), it is possible that practices or conditions at the fresh-cut facility contributed to the contamination event. It is possible that the way product is handled during processing, including mixing large batches of fresh-cut product, may spread contamination across a larger volume of product, impacting the size and scope of an outbreak associated with fresh-cut

produce. However, there have also been a number of very large outbreaks associated with RACs.

Pathogens associated with the produce outbreaks include bacteria, viruses and parasites. Between 1996 and 2010, the majority of fresh produce-related outbreaks and illnesses in the FDA database were associated with bacterial agents (86.5%), followed by parasites (11.6%) and viruses (1.9%). These outbreaks involved a number of pathogens, including *E. coli* O157:H7, *E. coli* O157, *Salmonella* species (*Salmonella* spp.), *Listeria monocytogenes (L. monocytogenes), Cyclospora, Shigella sonnei,* and Hepatitis A.

In an accompanying document titled ''Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce,'' FDA has conducted a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (hereafter referred to as the Qualitative Assessment of Risk (QAR)). In particular, the QAR is intended to address various risk management questions related to biological hazards of concern in fresh produce that can lead to serious adverse health consequences or death; potential routes of contamination; and the likelihood of contamination and likelihood of illness attributable to consumption among various types of produce commodities. The findings of this qualitative assessment of risk informed our regulatory approach and several proposed provisions. We provide a summary of the findings in section IV; additionally, we refer to the QAR throughout this proposed rule, including the discussion of proposed provisions in section V of this document.

B. Contamination With Chemical, Physical or Radiological Hazards

Chemical contaminants of produce can originate from a variety of sources. Most common among these include soil (through previous chemical exposure), equipment (*e.g.,* lubricants, fuels, and refrigerants), pesticides, insecticides and related agents, and cleaning compounds (*e.g.,* sanitizers) normally used in the course of maintaining buildings and equipment. FDA monitors chemical and pesticide residues in foods through its regulatory monitoring programs with emphasis on raw agricultural commodities (RACs) and foods consumed by infants and children. Illnesses attributable to chemical hazards are rare (Ref. 7). In fact, between 1997 and 2011, there have been no Class I recalls of produce associated with a chemical hazard for which there is a reasonable probability of causing serious health problems or death (Ref. 8). Current monitoring, regulations, and industry practice have been sufficient to keep these hazards under control.

Similarly, the potential public health consequences of physical hazard contamination (*e.g.* glass or metal fragments) in produce appear to be relatively (Ref. 7). Rarely do the physical hazards associated with produce suggest a risk of serious adverse health consequences or death for individuals that would consume the product. In fact, between 1997 and 2011, there have been no Class I recalls of produce associated with a physical hazard for which there is a reasonable probability of causing serious health problems or death (Ref. 8).

The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards, outside of catastrophic events, is very low (Ref. 7. Ref. 9).

While we acknowledge the potential for chemical, physical or radiological contamination of produce, based on our analysis (Ref. 7), and for the reasons discussed in section IV.B of this document, we are not proposing specific standards for these hazards in this rulemaking.

II. Efforts to Address Produce Safety

FDA and others have taken a number of actions to address produce safety in the last two decades. This section describes several of these activities up to and including FSMA.

A. Inspections and Investigations

We have conducted a number of inspections and investigations that have provided useful information about the routes of contamination. Investigations involved visiting multiple field locations and packing operations. Observations during the investigations revealed several areas of farm practices that seem most likely to have been possible routes of contamination for produce involved in the outbreaks. Our inspections, investigations, and surveillance sampling activities are described in more detail in accompanying documents.

B. Guidance Documents and Letters to Industry

1. GAPs Guide

On October 2, 1997, President Clinton announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (Produce and Imported Food Safety Initiative or PIFSI). As part of this initiative, the President directed the Secretary of the Department of Health and Human Services (HHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) for fresh fruits and vegetables. In October, 1998, we issued final guidance to industry entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs Guide) (Ref. 10). This guide contains voluntary recommendations for good agricultural practices (GAPs) that growers and packers can undertake to address common factors contributing to contamination in their operations. The GAPs Guide is a broad scope guidance that takes into account the diversity of conditions and practices associated with the growing, harvesting, packing and holding of fresh produce. We noted that firms should use the general recommendations in the GAPs Guide to tailor practices to their individual operations. As the GAPs Guide notes, current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw. Therefore, the focus of the GAPs Guide is on implementing measures to minimize the potential for introduction of such hazards.

On September 2, 2008, we issued a notice in the **Federal Register** (73 FR 51306) requesting comments and scientific data and information to assist us in improving the GAPs Guide. We specifically asked for information about (1) current agricultural practices and conditions used to produce, harvest, pack, cool, and transport fresh produce; (2) risk factors for contamination of fresh produce associated with these practices; and (3) possible recommendations or additional measures that would enhance the safety of fresh produce. We also requested information about the estimated costs and benefits of current practices and/or the cost and benefits of any recommendations. We received approximately two dozen submissions from organizations and individuals, including: Industry, government, universities, environmental groups, consumers, and consumer groups. A number of comments discussed the value of performing operational assessments, developing food safety plans and record keeping but suggested that any updated guidance acknowledge that these activities should be commensurate with the complexity of an operation and associated risks. Other

comments requested additional information on microbial testing to ensure that when testing is done it is meaningful and cost effective.

2. Letters to Lettuce, Tomato, and Cilantro Industries

On February 5, 2004, we issued a letter to firms that grow, harvest, pack or hold fresh lettuce and fresh tomatoes, expressing concern regarding outbreaks of foodborne illness associated with the consumption of these products, and recommending actions to enhance the safety of these products (Ref. 11). On November 4, 2005, we issued a second letter to firms that grow, harvest, pack, hold or manufacture/process fresh and fresh-cut lettuce, reiterating concerns about continuing outbreaks (Ref. 12). In the November 2005 letter, we strongly encouraged applicable firms to review their current operations in light of the GAPs Guide, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encouraged firms to consider modifying their operations to ensure that they were taking the appropriate measures to provide a safe product to the consumer. We recommended that firms from the farm level through the distribution level undertake these steps.

In March, 2011, we issued a letter to firms that grow, harvest, pack or hold fresh cilantro, expressing concern about positive sample findings and recommending actions to enhance the safety of these products (Ref. 13). Between 2004 and March, 2011, there had been 28 confirmed *Salmonella* positive sample results in fresh cilantro in, or entering into, commerce. Samples were of both U.S. and imported origin. As with earlier letters to the industry, we strongly encouraged applicable firms to review their current operations in light of the GAPs Guide, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encouraged firms to consider modifying their operations to ensure that they were taking the appropriate measures to provide a safe product to the consumer. In addition, we encouraged these firms to assess hazards unique to the production of cilantro and to develop commodity-specific preventive control strategies. We recommended that firms from the farm level through the distribution level undertake these steps.

3. Guidances and Letters Regarding Sprouts

On October 27, 1999, we published a notice of availability (64 FR 57893) for two guidance documents to inform all parties involved in the production of sprouts (*i.e.,* producers, conditioners, and distributors of seeds and beans used for sprouting, sprout producers) that sprouts have been recognized as an important cause of foodborne illness and to provide recommendations for preventive controls that we believed should be taken immediately to reduce the likelihood of sprouts serving as a vehicle for foodborne illness (Ref. 14).(Ref. 15) The first guidance document, ''Reducing Microbial Food Safety Hazards for Sprouted Seeds'' (the Sprout Guide), provides recommendations based on the recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (Ref. 16). We also released a second guidance, ''Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production'' (the Sprout Testing Guide), to assist sprouters in implementing one of the principal recommendations in the broader Sprout Guide, *i.e.,* that producers test spent irrigation water for two pathogens (*Salmonella* spp. and *E coli* O157:H7) before product enters commerce. We refer to these guidances collectively as the Sprout Guides.

On April 22, 2005, we announced in the **Federal Register** (70 FR 20852) a public meeting to elicit information on current science related to foodborne illness associated with the consumption of sprouts. The meeting notice contained a series of questions to help focus comments, including questions regarding: (1) Practices that may contribute to contamination of seeds used for sprouting and intervention strategies that could help prevent, reduce, or control contamination of seeds used for sprouting; (2) Whether the preventive controls recommended in our Sprout Guides could be improved and, if so, how this might be done; (3) What can or should be done to increase the involvement of producers of seeds for sprouting and seed distributors to ensure the safety of sprouts; (4) How, if at all, should the actions to improve the safety of seeds for sprouting be structured to take into account variation within the seed and sprout industry, including variations in size of establishments, the types of seeds and sprouts produced and the practices used in production; and (5) Existing food safety systems or standards (such as international standards) that we should consider as part of our efforts to minimize foodborne illness associated with the consumption of sprouts.

In general, comments expressed a need to include the seed industry, as well as the sprout industry, in efforts to improve the safety of sprouts. Several comments stated that any recommendations should be scientifically sound, based on appropriate (and feasible) expectations for risk reduction, and be easy to understand and implement. Comments expressed concern about the effect on worker health of treating seed with 20,000 ppm calcium hypochlorite. Comments were generally supportive of recommendations in the Sprout Guides to test spent irrigation water; several comments supported expanded testing, including seed testing by seed producers and distributors. All but one comment maintained that seeds were the primary source of contamination in sprout-associated outbreaks. Several comments discussed practices and conditions, such as animal grazing, which could contaminate seed in the field. One comment suggested the industry develop a GAPs guidance specific to the production of seed for use in sprouts. Several comments supported applying Current Good Manufacturing Practices (CGMPs) (21 CFR Part 110) to sprout facilities. A number of comments cited the diversity of sprout types currently being produced and noted this diversity of products is likely to continue to grow. These comments maintained it was therefore appropriate to provide flexibility for individual operations to select mitigations appropriate for the products they produce. Comments to the 2005 Sprout Public Meeting were considered in this rulemaking and will be further described when we discuss proposed provisions specific to sprouts in section V.M. of this document.

On May 1, 2009, we issued a letter to suppliers and distributors of seeds and beans used for sprouting, and sprouters, to make firms aware of our serious concerns with continuing outbreaks associated with the consumption of raw and lightly cooked sprouts and to urge firms to review their operations in light of our Sprout Guides and other available information (Ref. 17), and to modify their operations accordingly to ensure they are taking appropriate measures to provide a safe product to consumers. We also shared a May 1, 2008, letter from the California Department of Public Health (CDPH) to the California sprout industry outlining several critical areas of concern identified in recent investigations and CDPH recommendations for controlling hazards associated with those observations (Ref. 18).

4. Draft Commodity Specific Guidances

On August 3, 2009, we published a notice in the **Federal Register** announcing the availability for public

comment of draft commodity specific guidances (CSGs) for melons (74 FR 38437), tomatoes (74 FR 38438) and leafy greens (74 FR 38439). The draft CSGs are intended for growers, packers, processors, transporters, retailers, and others throughout the supply chain. The draft CSGs, if finalized, would provide a framework for identifying and implementing appropriate measures to minimize the likelihood of microbial contamination of tomatoes, leafy greens, and melons. The draft CSGs reflect both commodity specific information, such as recommendations for tomato repacking, and advances in collective thinking in broader areas, such as assessing potential hazards in and near the field before beginning production and immediately before harvest, and protecting and maintaining water quality at its source and during distribution and use. The draft CSGs are designed to complement our GAPs Guide and Fresh-cut Guide. On November 4, 2009, we published a notice in the **Federal Register**, extending to January 4, 2010, the comment period on the draft CSGs. We have not yet issued these guidances in final form.

In developing the draft CSGs, we relied heavily on existing industry commodity specific guidelines, our produce safety initiatives and programs, lessons learned from outbreak investigations, and other public and private programs. We have since received several dozen written comments, from industry, States, and individuals. Comments were generally supportive of the scope and objectives of the draft CSGs. Comments provided their views on both commodity specific issues (*e.g.,* recommendations for field packing tomatoes, water quality for rehydrating leafy greens after harvest) and cross-cutting issues (*e.g.,* management of wild animal intrusion, quality of water used in postharvest operations). A number of comments requested that we recognize different risks may be associated with different commodities within the commodity groups covered by the CSGs, noting, for example, that cantaloupe (not watermelon) have been identified as the vehicle in the majority of foodborne illness outbreaks associated with melons. A number of comments expressed concern about potential bias of the CSG approach (*i.e.,* separate recommendations for different commodities) against small farms growing a diversity of crops, especially the concern that the CSG approach could require such farms to have multiple food safety plans to cover each of the commodities they grow. Additional comments will be discussed when we describe proposed provisions relevant to those comments.

5. Guidances Regarding Nuts

On March 11, 2009, we published a notice in the **Federal Register** (74 FR 10598) announcing the availability for public comment of draft guidance for industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient. Additionally, on June 29, 2009, we published a notice in the **Federal Register** (74 FR 310308) announcing the availability for public comment of draft guidance for industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product As An Ingredient. These draft guidance documents were intended for manufacturers who use a peanut-derived product or pistachio-derived product as an ingredient in a food product. These draft guidances provide recommendations for evaluating the effectiveness of certain *Salmonella* control measures. We have not yet issued these guidances in final form.

6. Fresh-cut Guide

On March 6, 2006, we published a notice in the **Federal Register** (71 FR 11209) announcing the availability on our Web site of a draft Guidance for Industry entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables'' (the Fresh-cut Guide). We received a number of comments from trade associations, consumer groups, and industry. Comments were generally supportive of the draft Guide. A few comments included questions about our draft definition of fresh-cut produce and whether the recommendations in the draft guidance were mandatory or voluntary, in light of the mandatory requirements in existing CGMPs.

On February 25, 2008, we published a notice (73 FR 10037) announcing our finalization and the availability of our ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables'' (the Fresh-cut Guide). The Fresh-cut Guidance complements the CGMPs in 21 CFR, Part 110 and provides recommendations for a framework for identifying and implementing appropriate measures to minimize the likelihood of microbial contamination during the processing of fresh-cut produce. Examples of recommendations for fresh-cut processors in the Fresh-cut Guidance include: (1) Know your suppliers and have a mechanism to verify that your suppliers use good agricultural practices, good manufacturing practices, and other appropriate food safety practices; and (2) ensure equipment is designed to prevent water collection. While fresh-cut produce is not covered under the scope of this proposed rule, we include a reference to our guidance on fresh-cut produce as some of the measures recommended in that document are relevant to the requirements proposed for covered produce in this rule.

B. Produce Safety Action Plan

On June 15, 2004, we published a **Federal Register** notice (69 FR 33393) announcing a public meeting to elicit information from stakeholders concerning key elements of a draft produce safety action plan entitled ''Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce'' (the Produce Safety Action Plan or PSAP). We posted the draft PSAP on June 18, 2004 (Ref. 19). The draft PSAP continued the 1997 Produce and Imported Food Safety Initiative, building on experience from earlier efforts such as the development and implementation of the GAPs Guide, inspections of farms and produce packing facilities, surveillance sampling assignments, and investigations of foodborne illness outbreaks. The draft PSAP addressed all principal points between the farm and table where contamination of produce could occur. It covered fresh fruit and vegetables in their native (RAC) form and raw, minimally processed products (*i.e.,* fresh-cut produce) that have received some processing to alter their form but have not been subject to a thermal process that would eliminate microbial hazards. The draft PSAP was not intended to cover processed products such as juice, or agricultural products other than fruits and vegetables.

After considering comments received from various stakeholders, in October 2004, we issued the final PSAP. In recognition that contamination of produce can happen at any point in the supply chain, the PSAP expands on the areas covered by the GAPs Guide (*i.e.,* farms and packing houses) to extend to all parts of the food supply chain from farm through retail or consumer preparation and consumption. The PSAP does not cover frozen fruits and vegetables, fruit and vegetable juices, or nuts. The PSAP has four main objectives: (1) Prevent contamination of fresh produce with pathogens; (2) minimize the public health impact when contamination of fresh produce

occurs; (3) improve communication with producers, packers, processors, transporters, distributors, preparers, consumers, and other government entities about the safety of fresh produce; and (4) facilitate and support research relevant to the contamination of fresh produce. For each objective, the PSAP identifies steps or actions that could contribute to the achievement of that objective. The PSAP has measurable goals and outcomes, and several steps outlined in the PSAP are already in progress or have been completed. For example, we issued the Fresh-cut Guide and provided technical assistance to industry efforts to develop commodity specific supply chain guidance as part of the PSAP objective regarding prevention of contamination.

C. Public Hearings

On February, 27, 2007, we published a notice (72 FR 8750) of two public hearings, and request for comment, on the safety of fresh produce. In that notice, we stated that we believe that the measures outlined in the PSAP, the GAPs Guide, and other public and private sector actions, when implemented, can be effective in reducing the likelihood of microbial contamination of fresh produce. However, the fact that outbreaks of foodborne illness associated with fresh produce continue to occur supports the need for a close examination of: The extent to which these measures have been implemented; whether they have been effective when implemented properly; and, what additional or different interventions might be appropriate to reduce the likelihood of future outbreaks.

We held the public hearings to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to invite comments, data, and other scientific information about: Current practices used to grow, harvest, pack, hold, manufacture/process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and measures FDA could take to enhance the safety of fresh produce. The notice of hearings included a list of issues and questions to help focus comments and asked for scientific information and data. We received approximately 48 submissions from industry, government, universities, environmental groups, consumers, and consumer groups. Recurring comments included: The importance of activities to promote or enhance rapid, accurate traceback; strengthened coordination and communication between all sectors (*i.e.,* researchers, regulators, and industry) on available science and current unpublished data; and an integrated, multidisciplinary approach to identify best practices not currently incorporated by industry. A number of comments expressed concerns about the cost of third party audits and lack of standardization of such audits. Comments also indicated a desire for training. Comments were divided on whether we should continue to promote adoption of voluntary GAPs guidance or pursue rulemaking to establish mandatory requirements. Comments supporting mandatory requirements differed on what these requirements should look like; suggestions ranged from mandatory GAPs to a Hazard Analysis and Critical Control Point (HACCP)-like approach, or a combination of the two. Comments were in general agreement that, whatever regulatory approach was chosen, it should be consistent across the United States, based on sound science, and cover a broad range of commodities while being flexible enough to accommodate the needs of specific commodities, regions, operations, practices, and different sizes of operations.

D. Partnerships and Collaborations

1. Public and Private Standards

Because the GAPs Guide is voluntary, FDA and food safety partners in the public and private sectors have emphasized education and outreach to industry to promote adoption of the guidance. Buyer requirements that producers and other suppliers provide self- or third party audit verification that they are following the GAPs Guide have further promoted adoption of the guidance. We have worked with the fresh produce industry since the release of the GAPs Guide to promote its recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh produce. For example, in conjunction with the PSAP, we have provided technical assistance to industry in developing several industry commodity specific guidelines that cover the entire supply chain, including commodity-specific guidelines for melons, leafy greens, tomatoes, and green onions; these commodities together accounted for 70 percent of the foodborne outbreaks associated with produce between 1998 and 2009 (Ref. 3). These industry guidelines were in turn helpful to us in developing FDA's draft commodity specific guidances for the same commodities (see section II.B.4 of this document). Additional industry guidelines have been developed or are in progress for a broad range of commodities, including: strawberries, mushrooms, watermelon, potatoes, storage onions, and citrus.

We provided technical assistance to the Association of Food and Drug Officials (AFDO) to formulate a Model Code of Practice for the Production of Fresh Fruits and Vegetables (the Model Code) (Ref. 20). This work grew out of a request from the tomato industry in late 2006 to address outbreaks of foodborne illness attributed to fresh tomatoes. However, the AFDO Board believed that it was also important to address GAPs in the production of a broader range of fresh fruits and vegetables. Thus, AFDO convened a working group to develop a Model Code for produce safety during growing, harvesting, packing and holding that could be considered as a model for guidance and/or regulation by Federal and State regulatory bodies, and for collaboration among such parties and the industry. The Model Code does not address the additional processing steps that may occur at a fresh-cut or other processing facility, which is covered by the CGMPs in 21 CFR part 110. The Model Code focuses on minimizing the potential for contamination of fresh produce with pathogens.

Through cooperative agreement with Cornell University, FDA has, together with USDA AMS, established a jointly funded Produce Safety Alliance (PSA), based on the successful Seafood HACCP Alliance for Training and Education. The PSA is a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental food safety knowledge, starting in advance of this proposed rule and continuing after the final rule is promulgated. The PSA includes active participation from the produce industry and academic institutions nationwide. The curriculum development process has already started, through establishment of topic-specific working committees charged with identifying challenges to understanding and implementing GAPs on farms. This first phase of work, in advance of a final rule, is intended to assist farms, especially small farms, in establishing appropriate food safety measures, consistent with the GAPs Guide and other existing guidances, so that they will be better positioned when we issue a final rule establishing produce safety standards under section 419 of the FD&C Act. As this rulemaking progresses, the PSA materials will be modified, as needed, to be consistent with the requirements in the rule.

2. Foodborne Illness Investigations—Environmental Assessment Model

An ''environmental assessment,'' in the foodborne illness outbreak or food contamination setting, means an investigation that is triggered by an outbreak of foodborne illness or food contamination incident with the purpose of determining how the environment may have contributed to the introduction or transmission of pathogens or other hazards that caused illness or contamination. In addition to our more traditional investigational team approach, during this process we work collaboratively with a number of experts from CDC, State and local agencies, and industry.

In 2010, we conducted an environmental assessment in response to a foodborne illness outbreak involving 33 cases of STEC O145 infection in 5 States. While we have not made a definitive determination regarding how or at what point in the supply chain *E. coli* O145 contamination occurred, this assessment was important in a number of respects. As mentioned above, we worked collaboratively with a number of experts from CDC, State and local agencies, and industry. Working with this team, we assessed potential sources of *E. coli* O145 not just in the field of interest, but in the larger growing area surrounding the field of interest, along with the potential for *E. coli* O145 to be transported from a source in the surrounding area to the field where implicated lettuce was grown. This highly collaborative, systems-based approach allowed for the discovery of important environmental risk factors that would not typically be explored by conventional investigation methods (Ref. 21). On December 29, 2010, we posted a report, entitled ''Environmental Assessment: Non-O157 Shiga Toxin-Producing *E. coli* (STEC): Findings and Potential Preventive Control Strategies'' (Ref. 21), outlining the environmental assessment approach used in this investigation, our observations and tentative conclusions.

In 2011, we conducted an environmental assessment in response to a foodborne illness outbreak involving a total of 139 persons infected with any of four outbreak-associated strains of *L. monocytogenes,* including 29 deaths, in 28 States (as of November 1, 2011). On October 19, 2011, we posted a report, entitled ''Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis,'' providing an overview of the assessment process, potential contributing factors in this outbreak, and recommended measures firms should employ to prevent similar contamination (*http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm*). As discussed further in sections III.F and V.A.2.b.i of this document, this proposed rule would not apply to off-farm packing facilities such as the packing facility associated with this cantaloupe outbreak—such facilities would instead be subject to existing part 110 and section 418 of the FD&C Act. However, we include the findings of this environmental assessment here because the contributing factors are relevant to both on-farm and off-farm produce packing practices.

3. Produce Safety Initiative Assessments

In August 2006 we launched the Leafy Greens Safety Initiative (LGSI), a multi-year initiative which involved assessments of practices and conditions at select leafy greens farms and facilities in California (Ref. 22). In the summer of 2007, we began a multi-year Tomato Safety Initiative (TSI) to assess practices and conditions associated with growing and packing tomatoes on the Eastern Shore of Virginia, followed by assessments in three tomato growing areas in Florida (Ref. 23).

The initiatives were conducted as part of a strategy to reduce foodborne illness by focusing food safety efforts on specific products, practices, and growing areas that have been identified in past outbreak investigations. The initiatives were a collaborative effort between FDA and the State health and agriculture departments in California, Virginia, and Florida, in cooperation with several universities and members of the produce industry. Both initiatives contained several important components, the most visible of which was a series of assignments to the field to assess conditions and practices at farms and packing houses that could lead to contamination and to observe actions taken by growers and packers in response to these conditions. Other important components of the initiatives included continuing communication and outreach with the industry at all points along the supply chain, facilitating and promoting research to enhance leafy green and tomato safety, and strengthening collaboration between Federal, State, and local public health officials in disease detection and response.

Assessments of tomato packing facilities covered dump tank water quality parameters, employee hygiene, and facility cleaning and sanitation practices. Assessments of the farms addressed irrigation water sources (such as ponds and wells), source water and procedures for mixing crop chemicals, the potential impacts of weather events, such as drought and flooding, and animal proximity to growing fields. Assessments were scheduled to coincide with tomato production and harvest seasons on the Eastern Shore of Virginia and in three tomato producing regions in Florida.

Where the teams observed conditions or practices at one or more locations that might be improved, they shared those observations directly with the individual firm and also shared observations in general terms at a post-assessment meeting so that all interested parties could apply the findings to their operations. For example, we identified issues related to proximity of portable toilets to irrigating ponds and harvesting of drops at one or more locations. The teams recommended that portable toilets should be distanced from the irrigation pond and policies that forbid the harvesting of drops should be strictly enforced. We also shared preliminary observations through other venues, including a tomato research priorities meeting in College Park (hosted by Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the University of Florida's Institute of Food and Agricultural Sciences) (JIFSAN 2010 (update)), a Leafy Greens Research Needs workshop hosted by United Fresh in Herndon, VA (United Fresh 2008), and as technical assistance to public and private efforts to develop new or enhanced guidances.

4. Research

FDA researchers have focused on refining or developing methods to detect, isolate and subtype pathogens of concern in produce, to enhance our ability to analyze samples in support of our compliance activities. As resources permit, FDA scientists also directly investigate questions about factors contributing to produce contamination. We also supported extramural research and collaborations with other Federal agencies, academic institutions, and industry-supported entities to leverage research efforts, expertise, and resources (such as experimental stations for field research). This includes successful collaborations with USDA on research of mutual interest. To fill knowledge gaps, thus facilitating implementation of any new policies, we have initiated new agreements with USDA to conduct research in key areas such as agricultural water and soil amendments (Ref. 24). Specifically, FDA has provided approximately one million dollars to sponsor research at USDA

ARS and to develop a produce safety rule research network at the Western Center for Food Safety at University of California Davis. We intend these collaborative efforts to result in the collection of data that may help resolve questions about the necessary time between application of raw manure or contaminated water and safe harvest of produce in key agro-ecological growing conditions and for key crops. Our goal is for this research to result in suggested protocols that farms could follow in compliance with a final produce rule, and for this process to be duplicated for other crops and regions as further funding is secured. This FDA sponsored research was initiated to demonstrate the commitment of federal agencies to address the needs of farmers, to provide initial data to finalize study protocols for further research, and to attract matching funds from industry.

In partnership with academic institutions across the country, FDA has also created four Centers of Excellence (CoE), each housed at a university and charged with specific food-safety tasks (Ref. 25). In 2008, a 5-year cooperative agreement was awarded to the University of California, Davis (UC Davis) to establish the most recent of these CoEs, the Western Center for Food Safety (WCFS). Through this agreement, FDA has been able to leverage the resources and expertise of UC Davis to study the impact of the unique geography and ecology of the growing regions of the Western United States.

5. Engagement With Other Federal Agencies

FDA regularly consults and coordinates with other Federal agencies in the area of produce safety. Examples of these efforts can be found throughout this document and include collecting samples, sharing data, providing training and technical assistance to industry, and research. Our partnerships with USDA and CDC have been particularly valuable to our efforts.

6. Engagement with Industry and Academia

We regularly engage with experts in the produce industry and in academia. These engagements serve to both educate the industry about our thinking, activities, and expectations, and to educate us about current industry practices and academic efforts to enhance the safety of produce.

In addition to the collaborations mentioned above, we initiated multiple produce industry listening sessions across the country prior to the passage of FSMA. At these sessions, we provided local industry and academia an opportunity to ask questions and voice concerns about the potential for legislation impacting the produce industry. We visited a total of 13 States with significant produce production in 2010. FDA and USDA technical experts, scientists and managers participated in these meetings, and we were able to tour large and smaller scale farms, and talk to people with practical experience in production and implementing food safety programs on farms.

We also were involved with the Produce Safety Project (PSP), a research and advocacy organization based at Georgetown University and funded by the Pew Charitable Trust. The PSP provided four issue briefs (Ref. 26.Ref. 27.Ref. 28.Ref. 29) each focused on specific aspects of produce production, the risks they may represent, prevention and mitigation strategies to address these risks, and further research needs in the area. Further, PSP held 6 regional stakeholder discussion sessions to elicit comment and reaction from the produce industry, and to offer an avenue to speak directly to the documents' authors. A common message from the industry during these discussions was concern about food safety and a desire to know how to reduce risks. Small growers and packers in particular conveyed a need for information and technical support that would assist them in implementing food safety practices.

E. Current Industry Practices

In response to foodborne illnesses associated with produce in the mid 1990s, the produce industry developed produce safety guidance, engaged in outreach regarding produce safety best practices, developed compliance auditing programs, and funded produce safety research.

1. Industry Produce Safety Best Practices Guidance

In 1997, the International Fresh-cut Produce Association and the Western Growers Association published Voluntary Food Safety Guidelines for Fresh Produce, which provided generalized voluntary industry guidelines to minimize the potential for contamination for fresh produce in growing, packing, shipping and processing operations. After FDA issued our GAPs Guide, industry developed commodity specific guidances for various produce industry segments including: Commodity Specific Food Safety Guidelines for the Melon Supply Chain (2005), Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain (2006), Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain (2006 1st Edition, 2008 2nd edition) and Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions (2010). In addition, other industry segments including, but not limited to mushrooms, strawberries, watermelons, citrus, avocados, almonds, and dry bulb onions developed commodity specific guidances. The fresh-cut produce industry, via the International Fresh Produce Association, published in 1992 Food Safety Guidelines for the Fresh-cut Produce Industry and updated this publication periodically, with the 4th edition being published most recently in 2001.

2. Produce Industry Food Safety Compliance Auditing

Shortly after the FDA GAPs Guide was finalized, a number of retail produce buyers informed suppliers that as a condition of sale, their produce suppliers must follow, and be third party audited for conformance with, the FDA GAPs guide (Ref. 30). In 1999 USDA AMS began developing a GAPs and Good Handling Practices (GAP & GHP) Audit Verification Program, in response to requests from growers and the Association of Fruit and Vegetable Inspection and Standardization Agencies. The program, based on the GAPs Guide, was piloted in 2000 and fully available later that same year. In September 2001 the United Fresh Fruit and Vegetable Association published guidance entitled Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables to provide the basis for GAPs audits in the produce industry. In 2011 the United Fresh Produce Association published a Harmonized GAPs Standard for use by producers and third party auditors in the fresh produce industry.

In 2007 leafy greens growers in California, with the assistance of the USDA AMS and CDFA, developed and implemented the California Leafy Greens Marketing Agreement (CA LGMA) (Ref. 31). The objective of the CA LGMA is to protect public health via compliance with the food safety practices accepted by the LGMA board, verified through mandatory government audits of members and signatories to the agreement by CDFA auditors trained and licensed by USDA AMS (Ref. 31). In 2007 leafy greens growers in Arizona also adopted a similar marketing agreement and audit structure for their growers (Ref. 32). At the request of industry, the USDA AMS in 2009 held seven hearings throughout the United

States to solicit input from the leafy greens industries across the U.S. regarding their desire to develop a proposed national marketing agreement for leafy greens (74 FR 45565). A decision regarding the proposed USDA AMS national marketing agreement for leafy greens is currently pending.

In 2007, the Florida Legislature passed a law that provided the Department of Agriculture and Consumer Services with the authority to address safety concerns related to fresh tomatoes. Implementing regulations which became effective on July 1, 2008 (Florida Tomato Inspection Regulation 5G–6, 2007) adopted and incorporated by reference almost all of the recommendations in the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2nd Edition (July 2008).

GAPs implementation and GAPs audits have now become common components of purchase specifications for produce in some market segments, and have been a significant force in increasing awareness of GAPs and promoting their implementation (Ref. 33). However, growers and packers who sell product through direct marketing channels, or to buyers who do not include GAPs as a condition of sale, may be less familiar with GAPs.

3. Produce Industry Produce Safety Education Outreach

In addition to participation in the PSA housed at Cornell University (discussed above in section II.D. of this document), the produce industry promoted adoption and implementation of the recommendations in the FDA GAPs Guide through education and outreach efforts in cooperation with the land grant universities. The National GAPs Program at Cornell University, with collaborators at other land grant universities, developed a series of publications to train domestic growers and packers on the key principles of produce safety, including: Food Safety Begins on the Farm: A Grower's Guide (2000); Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks (2003); and, Fruits, Vegetables, and Food Safety: Health and Hygiene on the Farm (2004). These publications and others developed by land grant universities throughout the United States have been used to train the produce industry on produce safety best practices.

F. 2010 Federal Register Notice and Preliminary Stakeholder Comments

On February 23, 2010, we published in the **Federal Register** (75 FR 8086; 2010 FR notice) a notice opening a docket to obtain information about current practices and conditions for the production and packing of fresh produce. On May 20, 2010, we extended the original 90-day comment period for the docket until July 23, 2010 (75 FR 28263). We established this docket to provide an opportunity for interested parties to provide information and share views that would inform the development of (1) safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance.

In particular, we welcomed input on these general categories: (1) Role of the good agricultural practice recommendations in the GAPs Guide; (2) Standards for domestic and foreign growers and packers; (3) Identification and prioritization of risk factors; (4) Environmental assessment of hazards and possible pathways of contamination; (5) The impact of scale/size of growing operations on the nature and degree of possible food safety hazards; (6) Methods to tailor preventive controls to particular hazards and conditions affecting an operation; (7) Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations; (8) Coordination of produce food safety practices and sustainable and/or organic production methods; (9) Coordination of produce food safety practices and environmental and/or conservation goals or practices; (10) Coordination of produce food safety practices and Federal, state, local and tribal government statutes and regulations; (11) Microbial testing; (12) Postharvest operations and the role of the CGMPs in 21 CFR part 110; (13) Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce; and (14) Strategies to enhance compliance.

We further advised that information previously submitted to the dockets requesting comments on the draft commodity-specific guidances (CSGs), or to the docket requesting comments and scientific data and information to update the GAPs Guide, would be considered in this rulemaking and need not be resubmitted. Comments submitted to these dockets, *i.e.,* dockets on the GAPs Guide update and draft CSGs, as well as comments at the Sprouts Public Meeting and Produce Safety Hearings, are discussed in sections II.B. and II.D. of this document.

In response to the 2010 FR notice, we received about 880 comments from consumers, farmers and producers, industry groups and trade associations, consumer groups, environmental groups, academia, retail establishments, packers and handlers, food markets and coops, laboratories and public health facilities, and federal, state, local and foreign governments. The USDA Agricultural Marketing Service (AMS) submitted a record of their public hearings related to their proposed voluntary national marketing agreement for leafy green vegetables (NLGMA) (74 FR 45565, September 3, 2009 and 74 FR 48423, September 23, 2009), and requested that we consider the contents of that record (which included testimony, exhibits, and written arguments or briefs based on evidence received at the public hearing) in our deliberations to develop safety standards for fresh produce. A summary of general comments received is presented in this section while specific comments relevant to the issues addressed in this proposed rule are discussed in sections V.C through V.R of this document.

1. Comments on Impact, Flexibility and Transparency

Overall, a majority of stakeholders, including farmers, producers, consumers and industry, expressed concern about the scope and impact of regulation on the livelihoods of those who produce food and on their ability to produce food in an economically-feasible manner. Most comments supported a food safety system, grounded in science, for the production of produce in a fair and equitable manner for both domestic and imports. Comments noted that regulations developed should be science-based and provide for producers to manage risks in a manner appropriate to their operations. Several comments maintained that risk assessments, hazard assessments, operational assessments and development of food safety plans are vital tools for farmers to be able to demonstrate that the food safety practices they employ are effective. Conversely, others questioned the need for some industry segments, such as small farms or growers of ''low risk'' commodities to establish food safety plans. A majority of comments also stated that research is needed on various issues relevant to produce safety, including water quality, soil amendments, animals (both wildlife and domesticated), and worker health and hygiene. Comments urged the agency to tailor regulations to reflect variables such as farm size, markets served, growing conditions, and risk. In addition, comments highlighted the importance of transparency in the

development and implementation of food safety standards, and expressed that transparency provides regulators, buyers, and the public with the confidence they need to ensure that all reasonable and required practices have been put in place and that any specific producer or packer of produce is in compliance with required food safety practices. FSMA directs us to establish science-based minimum standards for produce safety. These standards are to include procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards into covered produce and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. As discussed in section IV below, FDA intends to adopt a regulatory approach that considers the risk posed by both the commodity and relevant agronomic practices, and provides the most appropriate balance between public health protection and flexibility. We recognize the need to incorporate appropriate flexibility within regulations to reflect the diversity of commodities and associated processes, practices, and conditions covered within the scope of this rule. For example, exemptions based on monetary value of food sold by the farm and direct farm marketing, commercial processing of commodities, and other criteria are reflected in proposed subpart A. Under certain specified conditions, qualified exemptions and associated modified requirements in a calendar year are also provided under proposed subpart A. In addition, proposed § 112.12 would establish a framework for alternatives to certain requirements of the rule. We realize that numerous differences exist among practices based on risk or agro-ecological conditions and therefore alternatives to certain requirements would be permitted when adequate and documented scientific data or information support such alternatives. Similarly, proposed subpart P sets procedures for a State or foreign country to request a variance from one or more requirements of this part when certain conditions are met, as required by Section 419(c)(2) of the FD&C Act. For example, a State or foreign country may consider that the historical performance of an industry within their jurisdiction (*e.g.,* as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance from some or all provisions of this proposed rule. In requesting a variance, among other things, the State or foreign country would submit information that, while the procedures, processes and practices to be followed under the variance would be different from those prescribed in this proposed rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the requirements of the final regulations (see proposed 112.173). FDA would encourage consideration of these kinds of submissions.

Furthermore, in addition to soliciting comments on the proposed regulation through this notice, we will be holding public meetings in diverse geographic areas of the United States to provide persons in different regions an opportunity to comment, as required under Section 419(a)(2) of the FD&C Act.

2. Comments on Environmental Considerations

Several comments pointed out that there are a number of state and federal laws and programs that relate to environmental stewardship, and noted that environmental conservation and food safety are not necessarily cross-competing goals. Comments favored a uniform regulatory approach among Federal, State, local and tribal governments' statutes and regulations, and recommended that we consider the work of other Federal agencies, including the Environmental Protection Agency, the Department of Agriculture, and the Department of the Interior in developing proposed requirements for produce to ensure such requirements do not unnecessarily inhibit co-management of food safety and environmental concerns. In this regard, a few comments stated that while co-management of food safety and sustainability may be considered, ultimately, food safety has to be top priority and it is unacceptable to sell unsafe food to customers.

Section 419(a)(3)(D) of the FD&C Act directs that this proposed rule take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies. As discussed further in Sections III.A.8 and V.I, we consulted with several Federal agencies in order to take into consideration conservation and environmental practice standards and policies established by those agencies. FDA also plans to work closely with Federal, State, and local agencies in implementing the final rule.

3. Comments on Guidance and Education

A majority of comments also expressed the need for guidance to assist stakeholders in implementing the requirements established in final regulations. Moreover, several comments stressed the importance of educational programs and incentives in any effective food safety system.

Section 419(e) of the FD&C Act requires FDA to publish updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce, in consultation with the Secretary of Agriculture, representatives of State departments of agriculture, farmer representatives, and various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities, including small businesses. In addition, section 419(e) of the FD&C Act requires FDA to conduct education and outreach regarding this guidance through public meetings in diverse geographical regions. FDA intends to provide ample opportunity for public consultation and input and will strive to develop stronger partnerships with the private sector to ensure optimal use of resources.

4. Comments Related to Foreign Producers

A number of foreign governments expressed concerns with the foreign producers' ability to comply with and FDA's enforcement of the regulation, stressing the need for transparency. Some comments requested we consider convergence with existing private schemes, such as the Global Food Safety Initiative and Global G.A.P to avoid duplication of efforts while others urged us to consider recognition of foreign governments' produce safety initiatives.

In implementing a final rule based on this proposed rule, we intend to provide equal treatment in the application, compliance, and enforcement of the proposed standards for foreign and domestic facilities. Recognizing that foreign farms in some countries may have difficulty in understanding the rule's applicability to them, we will partner with stakeholders to identify areas for outreach and technical cooperation to achieve greater understanding of the proposed provisions.

Furthermore, consistent with section 419(c)(2) of the FD&C Act, in proposed subpart P, we establish a procedure

whereby a State or foreign country could request a variance from one or more requirements proposed in the rule, where the State or foreign country determines that (1) the variance is necessary in light of local growing conditions; and (2) the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act, and to provide the same level of public health protection as the requirements of this rule (see section V.P. of this document).

G. White House Food Safety Working Group

In 2009, President Obama established a White House Food Safety Working Group to identify measures needed to upgrade our food safety laws for the 21st Century, coordinate Federal efforts, and develop short- and long-term agendas to make food safer. Specific objectives of this workgroup included: Fostering coordination of food safety efforts throughout the government and ensuring laws are being adequately enforced to keep the American people safe from foodborne illness. The workgroup was co-chaired by the Secretaries of the HHS and USDA. Participating agencies included FDA, USDA's Food Safety and Inspection Service (FSIS), CDC, the Department of Homeland Security, the Department of Commerce, the Department of State, EPA, and several offices of the White House.

On July 7, 2009, the workgroup released its report ''Implementing a National Public Health Approach to Food Safety: Report to the President.'' This report included recommendations for a new public health-focused approach to the safety of all food based on three core principles: (1) Prioritizing prevention, (2) strengthening surveillance and enforcement, and (3) improving response and recovery. Workgroup recommendations and White House directives specific to produce included (1) issuing commodity-specific guidances to reduce the likelihood of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens; and (2) taking steps (including seeking public comment) to establish required practices through regulation. The numerous steps we have taken in response to these directives are described throughout this section.

H. Other Related Issues

1. Tracking and Tracing of Produce

Our regulations in 21 CFR part 1, subpart J require that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. During an outbreak of foodborne illness, these records can help determine the source of the food implicated in the outbreak. Farms are excluded from the requirements of part 1, subpart J. We recently held public meetings to stimulate and focus a discussion about mechanisms to enhance product tracing systems for food in general (74 FR 56843; November 3, 2009) and for produce in particular (73 FR 55115; September 24, 2008). Section 204 of FSMA now directs us to take a variety of different actions that will enhance our ability to track and trace foods, including to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. Further efforts to enhance the tracking and tracing of food are outside of the scope of this proposed rule.

2. Transportation of Food

On April 30, 2010 (75 FR 22713), we published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM) as a first step in implementing the Sanitary Food Transportation Act of 2005 (SFTA). SFTA requires the Secretary of HHS to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. Section 111 of FSMA directs us to promulgate regulations to implement SFTA. We intend to focus our efforts directed to sanitary transportation practices as a separate rulemaking, already underway under the ANPRM. However, such efforts are outside of the scope of this proposed rule.

III. Legal Authority

FDA is proposing this regulation under the FD&C Act as amended by FSMA, and the Public Health Service Act (PHS Act).

A. Section 105 of FSMA and Section 419 of the FD&C Act

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) was signed into law. Section 105 of FSMA, Standards for Produce Safety, among other things, amends the FD&C Act to create a new section 419 with the same name.

Section 419(a)(1)(A) of the FD&C Act directs the Secretary of HHS, ''in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security,'' to ''publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.'' In addition to this broad direction in section 419(a)(1)(A), section 419(a)(3) establishes more specific requirements for the content of the proposed rule, including that the proposed rule:

- ''[P]rovide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities'' (section 419(a)(3)(A));
- ''[I]nclude, with respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water'' (section 419(a)(3)(B));
- ''[C]onsider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism'' (section 419(a)(3)(C));
- ''[T]ake into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies'' (section 419(a)(3)(D));
- ''[I]n the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents, including guidance

documents regarding action levels, and regulations under the FDA Food Safety Modernization Act'' (section 419(a)(3)(E)); and

• ''[D]efine, for purposes of [section 419], the terms 'small business' and 'very small business''' (section 419(a)(3)(F)).

Furthermore, section 419(b) of the FD&C Act establishes additional requirements that the final regulation:

• ''[P]rovide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks'' (section 419(b)(1));

• ''[P]rovide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States or the appropriate elected State official as recognized by State statute'' (section 419(b)(2)(A)); and

• ''[I]nclude a description of the variance process under [section 419(c)] and the types of permissible variances the Secretary may grant'' (section 419(b)(2)(B)).

In section 419(c), the FD&C Act establishes criteria for the final regulation, including that the final regulation:

• ''[S]et forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated under section 402'' (section 419(c)(1)(A));

• ''[P]rovide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses such as a small food processing facility co-located on a farm'' (section 419(c)(1)(B));

• ''[C]omply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the business, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations'' (section 419(c)(1)(C));

• ''[A]cknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods'' (section 419(c)(1)(D));

• ''[N]ot require a business to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices, except in the case of negotiated enforcement resolutions that may require such a consultant or third party'' (section 419(c)(1)(E);

• ''[P]ermit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to [section 419(c)(2) of the FD&C Act], where the State or foreign country determines that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 [of the FD&C Act] and to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(1)(F)); and

• Establish requirements relating to variances, including that:

○ ''A State or foreign country from which food is imported into the United States may in writing request a variance from the Secretary. Such request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]. The Secretary shall review such requests in a reasonable timeframe'' (section 419(c)(2)(A)).

○ ''The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons'' (section 419(c)(2)(B)).

○ ''The Secretary may deny a variance request if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulation adopted under [section 419(b) of the FD&C Act]. The Secretary shall notify the person requesting such variance of the reasons for the denial'' (section 419(c)(2)(C)).

○ ''The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(2)(D)).

In addition, section 105(c) of FSMA creates a new section 301(vv) in the FD&C Act (21 U.S.C. 331(vv)) to prohibit ''[t]he failure to comply with the requirements under section 419 [of the FD&C Act].''

1. Coordination and Consultation Requirements

Consistent with section 419(a)(1)(A) of the FD&C Act, FDA has coordinated with the Secretary of Agriculture and representatives of State departments of agriculture (Ref. 34. Ref. 35) and consulted with the Secretary of Homeland Security regarding this proposed rule.

2. Definitions of Small and Very Small Businesses

Section 419(a)(3)(F) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business.'' These terms are significant because section 419 of FSMA contains provisions specific to such entities.

• ''With respect to small and very small businesses* * * that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are low risk and do not present a risk of serious adverse health consequences or death, the Secretary may determine not to include production and harvesting of such fruits and vegetables in such rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to [section 419]'' (section 419(a)(1)(B) of the FD&C Act).

• ''[T]he regulations promulgated under [section 419 of the FD&C Act] shall apply to a small business* * * after the date that is 1 year after the effective date of the final regulation* * * [and] to a very small business* * * after the date that is 2 years after the effective date of the final regulation'' (section 419(b)(3) of the FD&C Act).

In section V.A. of this document, we discuss our proposed definitions of small and very small business. In section IV.K. of this document, we discuss our proposal to establish compliance dates for small and very small businesses that are three and four years, respectively, after the effective

date of the final regulation, with additional, more extended compliance dates for certain proposed provisions related to water. FDA has tentatively decided not to exempt or modify the requirements of the proposed rule with respect to small and very small businesses that produce and harvest certain types of produce based on a determination that such types of produce are low risk and do not present a risk of serious adverse health consequences or death using the discretionary authority provided by section 419(a)(1)(B). It is not necessary to use this discretionary authority in part because, as discussed in section V.A. of this document, FDA proposes in § 112.2 to exclude certain types of low risk produce from the coverage of this rule without regard to the business size of the farm producing and harvesting such produce. As discussed in section IV.C.2. of this document, these exclusions are based on our tentative conclusion that science-based minimum standards to minimize the risk of serious adverse health consequences or death from biological hazards in these commodities are not warranted. Another reason it is not necessary to use the discretionary authority in section 419(a)(1)(B) is because, as discussed in section V.A. of this document, FDA proposes in § 112.4 to apply this regulation only to businesses with an average annual monetary value of food sold during the previous three-year period of more than $25,000 on a rolling basis, based on a tentative conclusion that businesses with $25,000 or less in sales do not contribute significantly to the produce market (1.5% of covered produce acres) and, therefore, to the volume of production that could become contaminated. Accordingly, we tentatively conclude that imposing the proposed requirements on these businesses is not warranted because it would have little measurable public health impact. We note that such farms would continue to be subject to the applicable requirements of the FD&C Act.

3. Exemptions and Exceptions

Section 419(f)(1) of the FD&C Act establishes an exemption from the requirements under section 419 based on average annual monetary value of the food sold directly to ''qualified end-users'' (as defined in section 419(f)(4)) as compared to all other buyers and average annual monetary value of all food sold. Section 419(f)(2) establishes requirements for consumer notifications with respect to food from exempt farms, and section 419(f)(3) provides that the Secretary may withdraw the exemption in specified circumstances. In sections V.A and V.R of this document, we discuss proposed §§ 112.5 and 112.6, and subpart R, respectively, which would implement these provisions of the FD&C Act.

Section 419(g) of the FD&C Act states ''[t]his section shall not apply to produce that is produced by an individual for personal consumption.'' In section V.A. of this document, we discuss proposed § 112.2(a)(2), which would implement this provision.

Section 419(h) of the FD&C Act states ''[t]his section shall not apply to activities of a facility that are subject to section 418.'' In sections III.F and V.A.2.b.i of this document we discuss proposed § 112.4(a), which would implement this provision.

4. Intentional Adulteration

FDA proposes to implement section 105 of FSMA in two regulations, rather than a single regulation that covers all hazards relevant to produce. This rulemaking is not intended to address hazards ''that may be intentionally introduced, including by acts of terrorism.'' (§ 419(a)(3)(C) and (c)(1)(A) of the FD&C Act). FDA plans to implement section 105 of FSMA regarding such hazards in a separate rulemaking in the future, and intends to consult with the Secretary of Homeland Security in that rulemaking, as required by § 419(a)(1)(A) of the FD&C Act. FDA tentatively concludes that intentional hazards likely will require different kinds of controls and would be best addressed in a separate rulemaking.

5. Science-Based Minimum Standards Related to Specific Topics

Consistent with the provisions in Section 419(a)(3)(B) of the FD&C Act that requires us to establish ''science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water,'' this proposed rule addresses specific topics relevant to production and harvesting of produce on farms. We address standards related to soil amendments in subpart F; standards for hygiene in subpart D, standards for animals in the growing area in subpart I; and standards for water in subpart E. We address packaging as part of our proposed standards for harvest, packing, and holding activities in subpart K; and temperature controls as part of our proposed standards for agricultural water in subpart E.

6. Providing Sufficient Flexibility To Be Practicable

As required by section 419(a)(3)(A) and (c)(1)(B), this proposed rule would provide sufficient flexibility to be practicable for all sizes and types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and is appropriate to the scale and diversity of the production and harvesting of such commodities.

As discussed in section IV of this document, we have chosen a regulatory approach that provides significant flexibility. We propose a variety of different types of measures (including GMP-type measures, numerical standards, requirements to monitor and take action under certain circumstances, and written plans) to tailor the requirements of the proposed rule appropriately and to be practical for the diversity of farms and commodities that would be covered by the proposed rule.

Wherever possible, we have also attempted to fashion this regulation to be as flexible as possible to accommodate future changes in science and technology and the particularities of local growing conditions and commodities. As discussed in section V.B of this document, in proposed § 112.12, we list the specific requirements established in this rule for which we would allow alternatives to be established and used in appropriate circumstances. This provision would provide significant flexibility by allowing individual farms to develop alternative standards suitable to their operations with appropriate scientific support. In addition, consistent with sections 419(c)(1)(F) and (c)(2) of the FD&C Act, in proposed subpart P, we provide for a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more requirements proposed in this part, where the State or foreign country determines that: (a) The variance is necessary in light of local growing conditions; and (b) the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part. Proposed subpart P would provide additional flexibility for alternative practices to be used where appropriate to specific local growing conditions and commodities.

7. Use of Third Parties

In accordance with section 419(c)(1)(E) of the FD&C Act, we are not proposing to require a farm to hire a consultant or third party to identify, implement, certify, or comply with these produce safety standards. These standards are intended to be capable of implementation by those who engage in routine activities on the farm. As discussed in section II.D.1 and V.Q., FDA has, together with USDA AMS, established a jointly funded Produce Safety Alliance (PSA), a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental food safety knowledge. Education and outreach through mechanisms like PSA and other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities and trade associations) is the foundation of our intended compliance strategy. Through these mechanisms, FDA aims to assist farmers in gaining the food safety knowledge they will need to comply with the provisions of a final produce safety rule.

8. Consideration of Environmental Standards

As required by section 419(a)(3)(D), in developing these produce safety standards and consistent with ensuring enforceable public health protection, we took into consideration conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies. In developing this rule, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA to take into consideration conservation and environmental practice standards and policies established by those agencies (Ref. 34). Our proposed requirements encourage the application of practices that can enhance food safety, including sustainable conservation practices. Additionally, as discussed in section V.E of this document, this proposed rule is designed to be compatible with existing conservation practices in the management of agricultural water systems. Moreover, as discussed in section V.I of this document, this proposed rule would not require the destruction of habitat or the clearing of farm borders around outdoor growing areas or drainages.

9. Consistency With National Organic Program

In accordance with section 419(a)(3)(E), this proposed rule does not include any requirements that conflict with or duplicate the requirements of the National Organic Program. In developing this proposed rule, we consulted with technical experts and representatives from the National Organic Program (Ref. 34). Compliance with the provisions of this proposed rule would not preclude compliance with the requirements for organic certification in 7 CFR part 205. Moreover, where this proposed rule and the National Organic Program would include similar or related requirements, we propose that our requirements may be satisfied concurrently with those of the National Organic Program (*i.e.,* to the extent the requirements are the same, compliance with this proposed rule could be achieved without duplication). For example, proposed § 112.54(c) would establish multiple options for composting processes used to treat biological soil amendments of animal origin used to grow covered produce, including two options (§ 112.54(c)(1) and (2)) that are consistent with the options available to USDA-certified organic farms under the National Organic Program regulations in 7 CFR 205.203(c)(2).

As another example, the National Organic Program application intervals for the use of raw manure as a soil amendment in 7 CFR 205.203(c)(1) are 90 days and 120 days before harvest, depending on whether the edible portion of the crop contacts the soil. Proposed § 112.56(a)(1)(i) would require a 9 month application interval for use of raw manure in the growing of covered produce when application is performed in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. Proposed § 112.56(a)(1)(ii) would not require an application interval for use of raw manure in the growing of covered produce when application is performed in a manner that does not contact covered produce during or after application. For certified organic farms growing produce that would be subject to this rule, the National Organic Program application intervals would run concurrently with the proposed application interval in this proposed rule, rather than consecutively. Organic farms (like other farms) using raw manure would either need to wait 9 months between application and harvest and use application methods meeting the proposed requirements for avoiding and minimizing contact between covered produce and raw manure, or apply the raw manure in a manner that does not contact covered produce during or after application. Doing so would not jeopardize their compliance with the requirements of the National Organic Program.

In addition, this proposed rule would establish in proposed § 112.163 that records kept for other purposes could be used to satisfy the recordkeeping requirements in this proposed rule. Accordingly, records kept under 7 CFR 205.103 for the purposes of the National Organic Program that contain information that would be required in records under this proposed rule would not need to be duplicated.

Further, while not critical to our conclusion regarding compliance with section 419(a)(3)(E) of the FD&C Act, we note that the provisions of the proposed rule are not in conflict with or duplicative of the non-binding recommendations of the National Organic Standards Board's Compost Tea Task Force (Ref. 36). Certified organic farms would be able to comply with the provisions of this proposed rule with respect to their use of agricultural teas while simultaneously meeting or exceeding the non-binding recommendations in the NOSB Compost Tea Task Force Report.

We seek comment on our approach to ensuring that this proposed rule does not conflict with or duplicate the requirements of the National Organic Program while providing the same level of public health protection as required under FSMA.

10. Minimizing PRA burden

In implementing section 419 of the FD&C Act through this proposed rule, FDA has complied with chapter 35 of title 44, United States code (commonly known as the ''Paperwork Reduction Act'' (PRA)), with special attention to minimizing the burden (as defined in section 3502(2) of such Act (44 U.S.C. 3502(2)) on the facility, and collection of information (as defined in section 3502(3) of such Act (44 U.S.C. 3502(3)), associated with the proposed rule. Under section 3502(2) of the PRA, ''burden'' means the ''time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency.'' Under section 3502(3) of the PRA, ''collection of information'' means, in relevant part, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for * * * answers to identical questions

posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons.* * *'' In section X of this document, we discuss how this proposed rule complies with the requirements of the PRA. In addition, in implementing section 419 of the FD&C Act, we have paid special attention to minimizing burden and collection of information associated with this proposed rule.

As discussed above, we are proposing requirements that provide significant flexibility for different sizes and types of farms. By making these requirements flexible enough to be practicable for different sizes and types of farms, the proposed rule also avoids creating unnecessary information collection burden for entities, because farms should be able to tailor their recordkeeping to their specific circumstances while still complying with the requirements of the proposed rule.

In addition, as discussed in section IV.E. of this document, the only requirements we are proposing that constitute collections of information are those that are necessary to implement section 419 of the FD&C Act and for the efficient enforcement of the FD&C Act. We propose to require records under this rule only in instances where maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of a known or reasonably foreseeable hazards, where identification of a pattern of problems is important to minimizing the risk of such hazards, or where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records. These instances are discussed in more detail in section IV.E. of this document and throughout section V of this document. In addition, although we recognize their value and encourage their use, we are not proposing to require farms to conduct operational assessments or to develop written food safety plans akin to similar requirements for facilities subject to section 418 of the FD&C Act or our juice HACCP or seafood HACCP regulations.

B. Other Provisions of the Federal Food, Drug, and Cosmetic Act

FDA's authority for this proposed rule also derives from sections 402(a)(3), 402(a)(4), and 701(a) of the FD&C Act. Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule includes many requirements that are necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, *e.g.,* regulations to require HACCP systems for fish and fishery products (21 CFR Part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy Salmonella organisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115), and regulations for the production, storage, and transportation of shell eggs (part 118).

C. The Public Health Service Act

In addition to the FD&C Act, FDA's legal authority for the proposed rule derives from the PHS Act. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) The provisions in the proposed rule are necessary to prevent food from being contaminated with human pathogens such as Salmonella, L. monocytogenes, and E. coli O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II of this document, without appropriate prevention steps, certain practices on farms can lead to the contamination of food with pathogens, increasing the likelihood of foodborne illness. We tentatively conclude that the proposed provisions in this document are necessary to prevent the spread of communicable disease and to prevent food from containing filthy, putrid, or decomposed substances; being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

D. Legal Authority for Records Requirements

We are proposing to use our authority under the FD&C Act and the PHS Act to institute certain records requirements as follows:

- For covered produce that is exempted from the requirements of the proposed rule because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance, the identity of the recipient that receives this produce (§ 112.2);
- For alternatives that farms may establish and use for certain requirements of the proposed rule, the scientific data and information used to support such alternatives (§ 112.12);
- Documentation of compliance with certain requirements related to training of personnel (§ 112.30); water monitoring and testing (§ 112.50); biological soil amendments of animal origin (§ 112.60); sanitizing of equipment used in growing operations for sprouts, or for covered harvest, packing, or holding activities (§ 112.140), and sprouts (§ 112.150); and
- General requirements in subpart O that apply to records required to be established and maintained.

As discussed further in sections V.A., V.B., V.C., V.E., V.F., V.L., V.M., and V.O. of this document, the proposed recordkeeping requirements are necessary for covered farms to ensure their own compliance with these aspects of the proposed rule and for FDA to ensure that covered farms are complying with the same aspects of the proposed rule. Therefore, these proposed requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both farms and FDA in ensuring that food is not adulterated, and are necessary to prevent the spread of communicable disease because they will aid both farms and FDA in ensuring that food does not

become contaminated with human pathogens.

In addition to having the authority under the FD&C Act and the PHS Act to require this recordkeeping, we also have the authority to require access to the records. Because the underlying requirements are necessary to minimize the likelihood of adulteration and the spread of communicable disease, access to records that demonstrate that a farm has followed those requirements is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow up regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent adulteration and the spread of communicable disease. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

F. Intrastate Activities

FDA tentatively concludes that the provisions in the proposed rule should be applicable to activities that are intrastate in character. The plain language of section 419 of the FD&C Act directs FDA to establish science-based minimum standards for the safe production and harvesting of fruit and vegetable RACs to minimize the risk of serious adverse health consequences or death. Section 419 does not include a limitation to interstate commerce. In addition, the exemption provided in section 419(f) of the FD&C Act, based in part on the proportion of a farm's sales made to restaurants or retail food establishments intrastate or within 275 miles, suggests that Congress intended the rule issued under section 419 to apply to intrastate commerce because otherwise there would be no need to provide an exemption for farms whose sales are intrastate in character. In addition, section 301(vv) of the FD&C Act provides that ''[t]he failure to comply with the requirements under section 419'', or the causing thereof, is a prohibited act. Section 301(vv) does not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 419 and 301(vv) of the FD&C Act as not limiting the application of the proposed rule only to those farms with a direct connection to interstate commerce.

FDA is mindful that its interpretation of FSMA and the FD&C Act should not cast doubt on the constitutionality of those statutes. (See *Solid Waste Agency of Northern Cook County* v. *U.S.,* 531 U.S. 159 (2001)). FDA has considered the relevant provisions of FSMA and the FD&C Act, FDA's responsibilities in implementing those statutes, and the law interpreting the commerce clause of the Constitution (Article I, section 8). Congress's power to legislate under the commerce clause is very broad. However, such power is not without limits, see *United States v. Lopez,* 514 U.S. 549, 567 (1995); *U.S.* v. *Morrison,* 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in *Lopez,* supra, the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn,* 317 U.S. 111 (1942), noting that ''although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of Federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.''' (514 U.S. at 556.) See also *Gonzales* v. *Raich,* 545 U.S. 1, 17–25 (2005). This principle applies to the application of sections 419 and 301(vv) of the FD&C Act, as added by section 105 of FSMA. Accordingly, given the collective impact on commerce of farms that grow, harvest, pack, or hold food that is sold in ''intrastate'' commerce, FDA tentatively concludes that such farms should be subject to the proposed rule unless an exemption from the rule applies (for example, if the farm is eligible for the qualified exemption in proposed § 112.5, or if the farm only grows produce exempt from the regulation under one of the exemptions in proposed § 112.2). This outcome is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that in any action to enforce the act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with FSMA's risk-based, preventive approach to food safety because the risk presented by unsafe food can be great, whether or not the food moves from one state to another. FDA seeks comment on the number of so-called ''intrastate'' farms that would not be exempt from the proposed rule either under the proposed exemption in § 112.5 or as a result of growing only produce that would be exempt under proposed § 112.2.

E. Relevance of Section 415 of the FD&C Act to ''Farm'' Definition and Related Definitions

Section 419 directs FDA to issue a proposed rule ''for the safe production and harvesting'' of certain produce. Section 419 does not affirmatively identify the businesses to which the proposed rule must apply, but requires FDA to address ''with respect to growing, harvesting, sorting, packing, and storage operations * * * soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water'' (419(a)(3)(B)); frequently uses the term ''farm'' (*e.g.,* section 419(f)); and clarifies that section 419 does not apply to produce produced by an individual for personal consumption (section 419(g)) or activities of facilities subject to section 418 (section 419(h)). FDA intends to issue a notice of proposed rulemaking implementing section 418 of the FD&C Act (section 103 of FSMA) in the near future. FDA tentatively concludes that ''activities of facilities subject to section 418'' are those activities triggering the requirement to register with FDA under section 415 of the FD&C Act (21 U.S.C. 350d), ''Registration of Food Facilities.'' FDA therefore tentatively concludes that it is reasonable to apply this proposed rule to farms and activities of farm mixed-type facilities that are within a definition of ''farm'' consistent with that utilized in FDA's implementation of section 415 of the FD&C Act, except to the extent that such entities are producing fruits and vegetables for their own consumption. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of the produce safety proposed rule. Ultimately, FDA intends that the activities to be regulated under this proposed rule will not trigger the requirement to register under section 415 of the FD&C Act and as a result will not be ''activities of a facility subject to section 418,'' consistent with the requirement in section 419(h). Moreover, the activities within the definition of ''farm'' we propose as part of this rulemaking closely track those identified in section 419(a)(3)(B), and

this interpretation is consistent with section 419(f)'s use of the term ''farm.''

Because section 418(o)(2) of the FD&C Act defines the term ''facility'' for the purposes of section 418 to mean only those facilities required to register under section 415 of the FD&C Act, FDA tentatively concludes that Congress intended the exemptions from the registration requirement set forth in section 415 and FDA's implementing regulations in part 1, subpart H (including the farm exemption in § 1.226(b)) to be meaningful for the purposes of defining section 418's applicability (and in turn, section 419's applicability). Thus, we tentatively conclude that activities within a definition of ''farm'' consistent with the definition utilized to implement the section 415 registration requirement are not subject to section 418 of the FD&C Act, but activities outside such a definition of ''farm'' are subject to section 418 when they cause a facility to be required to register with FDA under section 415. We discuss the proposed definition of ''farm'' and related definitions in section V.A.2.b.i of this document. We seek comment on these interpretations.

IV. Regulatory Approach

A. Qualitative Assessment of Risk

As discussed below, we are proposing to adopt an approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting only the lowest-risk produce. We conducted a qualitative assessment of risk (QAR) of hazards related to produce production and harvesting. The QAR indicated that produce commodities are potentially subject to similar microbiological hazard pathways: Commodities can potentially become contaminated from, for example, direct exposure to contaminated water or soil amendment. Therefore, we propose to adopt a regulatory approach for minimizing the risks associated with those hazards and, as appropriate, provide flexibility for the use of alternative measures that would provide the same level of public health protection as the proposed standard.

The QAR addressed various questions related to produce safety, including: (1) What are the biological hazards of concern in produce that can lead to serious adverse health consequences or death? (2) How does produce become contaminated (*i.e.,* routes of contamination) during on-farm growth, harvesting, and postharvest operations? (3) Does the likelihood of contamination vary among produce commodity types? (4) Does the likelihood of illness attributable to produce consumption vary among produce commodity types? (5) What is the impact of postharvest practices on the level of contamination at consumption? (6) What on-farm interventions are available to reduce the likelihood of contamination? (Ref. 2). The qualitative assessment of risk document is currently being peer reviewed and changes can be reasonably anticipated based on the peer review. The peer review plan is available online at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm*. We will consider peer reviewers' and public comments in finalizing the qualitative assessment and this proposed rule.

While data and information available to us at this time permitted us to conduct only a qualitative (not quantitative) assessment, some important conclusions can be drawn, which provide a basis for our proposed science-based minimum standards for the safe production and harvesting of produce commodities. We provide below a brief summary of conclusions of the QAR.

Key conclusions from this assessment are:

- Produce can be contaminated with biological hazards, and the vast majority of produce-related illnesses are associated with biological hazards.
- The most likely routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed (for sprouts), water, soil amendments, animals, worker health and hygiene, and buildings/equipment.
- Although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of these potential routes of contamination.
- The specific growing, harvesting, and on-farm postharvest conditions and practices associated with a produce commodity influence the potential routes of contamination and the likelihood that the given route could lead to contamination and illness. Use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.
- Postharvest practices such as cooking (and, possibly certain peeling) before consumption may have an impact on the likelihood of contamination of the edible portion and the likelihood of illness.

Hazards of concern in produce—The scientific evidence from outbreaks, surveys and published literature establish that human pathogens (*e.g.,* Salmonella, pathogenic E.coli, Shigella, Cyclospora) constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption.

Potential routes of contamination—Based on our observations during inspections, investigations, and surveillance activities and other available information, we have grouped the possible routes of contamination into five major pathways: Water, Soil amendments, Animals, Worker health and hygiene, and Equipment and buildings. Seed is an additional route of contamination for sprouts.

Likelihood of contamination—All produce commodities can be contaminated before, during, and/or after harvest through one or more of the potential routes of contamination. Although the likelihood of contamination varies by commodity, it appears to be dependent on the practices employed and, to a lesser extent, on the characteristics of the commodity. There appears to be greater variability in the likelihood of contamination among commodities during growing than during harvest or after harvest.

Likelihood of exposure—Subsequent to any contamination on-farm, consumer and retail handling practices and produce consumption rates affect the likelihood that consumers will be exposed to contamination. Postharvest practices such as cooking (and possibly certain peeling) before consumption may have an impact on the likelihood of exposure if indeed the produce is contaminated.

Risk of illness—Contaminated produce has the potential to cause illness. However, there are differences among commodities in the risk of illness primarily based on the routes of contamination associated with the commodity.

Produce commodities that are ranked as ''higher'' risk of illness and those ranked as ''lower'' risk of illness share some of the same characteristics. Both categories include:

- Crops where the harvestable portion grows in the ground;
- Row crops where the harvestable portion grows on or near the ground;
- Crops where the harvestable portion grows above the ground;
- Crops where the harvestable portion grows on trees, high above the ground; and

• Crops that are generally grown without soil.

Such diversity suggests that sorting commodities for risk based only on the manner in which commodities grow would be inappropriate. This diversity also characterizes commodities associated with outbreaks. Even within a commodity group, physical characteristics (such as texture of the fruit) of the commodity that could alter the potential for contamination and, therefore, association with an outbreak, do not always appear to do so.

In summary, some produce types are repeatedly associated with reported foodborne illness whereas other produce types are only intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: Agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

With regard to water as a route of contamination:—

• Agricultural water can be a source of contamination of produce.

• Public Drinking Water Systems (domestically regulated by the EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.

• Groundwater has the potential to pose a public health risk, despite the regulation of many U.S. public wells being subject to regulation under the Ground Water Regulation.

• There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.

• Susceptibility to runoff significantly increases the variability of surface water quality.

• Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.

• Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.

• Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.

• Commodity type (growth characteristics, *e.g.* near to ground) and surface properties (*e.g.,* porosity) affect the probability and degree of contamination.

• Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

With regard to soil amendments as a route of contamination—

• Soil amendments can be a source of contamination to produce

• Biological soil amendments of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste (*e.g.,* plant-based soil amendments).

• Human waste is the most likely waste to contain human pathogens.

• Animal waste subject to treatments, such as chemical and physical treatments and composting, has relatively lower levels of human pathogens than untreated animal waste.

• Composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste.

• Incompletely treated, or re-contaminated, biological soil amendments of animal origin may also contain human pathogens.

• Human pathogens in untreated or composted biological soil amendments, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

• Treatments, such as chemical and physical treatments and composting, can effectively reduce the levels of human pathogens in animal waste.

• Among application methods, application of soil amendments in a manner in which they contact the harvestable portion of the crop presents the greatest likelihood of contamination, especially when applied close to harvest.

With regard to animals as a route of contamination—

• Animals can be a source of contamination to produce.

• Animal excreta poses a high likelihood of contamination of produce.

• Excreta from domesticated animals poses a greater likelihood of contamination of produce than does excreta of wild animals. However, domesticated animals can be expected to be more readily controlled (*i.e.,* kept apart from produce growing, harvesting, and postharvest areas).

• Excreta from wild animals that rarely associate with human activities poses the least likelihood of contamination of produce.

• Human pathogens from animal excreta, once introduced to the growing environment, can be expected to eventually die off; but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors.

With regard to worker health and hygiene as a route of contamination—

• Humans (*i.e.,* workers and visitors) are potential carriers of foodborne pathogens and can be a source of contamination of produce.

• Individuals with communicable diseases that can be spread via food who are engaged in activities in which they contact produce or food contact surfaces can result in contamination of the produce or food-contact surfaces with human pathogens.

• Hand-washing reduces the potential for contamination of produce. Its efficacy varies depending upon the use of soap, the quality of the water, and whether or not hands are dried after washing.

• Dirty and damaged gloves may contaminate produce.

• Workers or visitors that touch animals can contaminate produce or food contact surfaces.

• Poor hygienic practices, *e.g.* lack of hand washing, can lead to contamination of produce.

• The presence of adequate toilet facilities in reasonable proximity to growing areas can reduce produce contamination.

With regard to equipment and buildings as a route of contamination—

• Food contact surfaces are potential routes of contamination of produce.

• Food contact surfaces such as equipment that are designed and constructed to be cleanable minimize the potential for contamination of produce.

• Pests in buildings used to grow or pack produce can be a source of contamination of produce.

• Waste material can be a source of contamination, or may become an attractant for pests and thereby act as a source of contamination to produce, if not properly contained, stored, and conveyed.

The provisions proposed in section V of this document reflect the above conclusions drawn from our qualitative assessment of risk. We seek public comment on the QAR, conclusions drawn from that assessment, and our consideration of those conclusions in

developing the proposed requirements. We also request you to submit any data or factual information that may help the agency to conduct, as warranted, a thorough and robust quantitative assessment of risk associated with produce production and harvesting practices.

B. Focus on Biological Hazards

Section 419 of the FD&C Act directs us to establish science-based minimum standards for the safe production and harvesting of those types of fruit and vegetable raw agricultural commodities (RACs) for which we determine that such standards minimize the risk of serious adverse health consequences or death (section 419(a)(1)(A) of the FD&C Act). These standards are to be based on known safety risks and to include procedures, processes, and practices that we determine to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards into fruit and vegetable RACs and to provide reasonable assurances that produce will not be adulterated under section 402 of the FD&C Act (sections 419(b)(1) and 419(c)(1)(A) of the FD&C Act).

As discussed in the QAR, available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. By contrast, chemical, physical, and radiological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product (Ref. 7). Section 419(c)(1)(A) of the FD&C Act requires FDA to ''set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards * * * and to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act].'' The frequency and nature of chemical, physical, and radiological hazards in produce are such that promulgation of a new regulatory regime for their control does not, at this time, appear to be reasonably necessary to prevent their introduction into produce or to provide reasonable assurances that produce will not be adulterated under section 402 of the Act. FDA tentatively concludes that existing programs, such as EPA registration of pesticides, and State and industry efforts to control the presence of pesticides and mycotoxins in produce, are sufficient to keep these hazards under control. In addition, under its broader food safety regulatory framework, FDA monitors natural toxins (*e.g.,* mycotoxins), pesticides, industrial chemicals (such as dioxins; cooking or heating related chemicals, such as acrylamide), and other chemical contaminants, and radionuclides in foods.

For these reasons, we tentatively conclude that the proposed rule should be limited in scope to biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards. Because of the proposed rule's focus on biological hazards, and because of the effectiveness of cooking and similar processes on the reduction of the likelihood of contamination of such hazards, as described in the Qualitative Assessment of Risk, we also propose to exempt produce that is rarely consumed raw or that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (see section V.A. of this document).

We request comment on this approach, and specifically on whether there are practices that are reasonably necessary to prevent the introduction of known or reasonably foreseeable chemical, physical or radiological hazards into produce or otherwise to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act because of chemical, physical, or radiological hazards. For example, proposed § 112.11 would require covered farms to take appropriate measures to minimize risks of serious adverse health consequences or death from the use of, or exposure to, covered produce attributable to biological hazards that may arise unexpectedly and therefore not be reflected in a specific standard set forth in proposed subparts C to O of this rule, or when there are biological hazards specific to a covered farm's location or circumstances for which such measures would be appropriate. Should § 112.11 also apply, for example, in the event of an accident or other unexpected event, such as a likelihood of radiological contamination relevant to a covered farm's location, to require that the covered farm take appropriate measures to prevent the introduction of radiological hazards into or onto the produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act? Such measures might include, for example, preventing covered produce from entering commerce if it may have been contaminated with radiological hazards that may render it injurious to health. As another example, if a covered farm's land was previously used for another activity that may have contaminated the soil with chemical hazards such that using the land to grow covered produce may cause introduction of those hazards into or onto the covered produce, should proposed § 112.11 require the covered farm to take appropriate measures to prevent the introduction of the chemical hazards into or onto the produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act? Such measures might include, for example, collecting and analyzing soil samples for residues of pesticides that are typically used in the production of cotton, if you intend to use a former cotton field for produce production. We seek comment on whether, and to what extent, chemical, physical, or radiological hazards should be covered within the scope of this rule.

C. Consideration of Differing Risk of Different Commodities and Practices

Section 419 of the FD&C Act also directs us to establish requirements that would provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruit and vegetable RACs, including small businesses and entities that sell directly to consumers, and to be appropriate to the scale and diversity of the production and harvesting of such commodities (section 419(a)(3)(A) of the FD&C Act). Section 419 further directs us to acknowledge differences in risk while minimizing, as appropriate, the number of separate standards we apply to separate foods (section 419(c)(1)(D) of the FD&C Act). We considered different approaches to determine how we might most appropriately respond to these directives, informed by the information contained in the Qualitative Assessment of Risk. These primarily included:

- Commodity-specific approach—covering only those produce commodities or commodity groups that might be described as posing a relatively higher risk of foodborne illness or applying different requirements to commodity categories based on relative risk of foodborne illness represented by the commodity category (such as higher, moderate and lower risk). A benefit of opting to pursue a commodity specific

approach would be a reduction in the costs of the proposed rule. Some commodities have little or no history of links to foodborne illness and, thus, exempting them from coverage could reduce costs to farmers with little or no reduction in calculated benefits from the rule. However, because foodborne illness outbreaks have regularly been associated with commodities that have previously not been linked to outbreaks, this approach carries the risk of failing to prevent future outbreaks.

• Integrated approach—covering all produce commodities except those that pose little or no risk of foodborne illness and then applying the most stringent requirements to agricultural practices that pose the greatest likelihood of contamination of the produce, regardless of the covered produce commodity. A benefit of selecting this option is that we would cover all commodities except those that pose little or no risk of foodborne illness, an approach that takes into account the sporadic and unpredictable nature of illness outbreaks, while still being sensitive to risk.

As discussed below, we explored both approaches thoroughly using information available to us at this time, and propose to use an integrated approach. Based on available data, we have not been able to fully develop a commodity-specific approach that we believe would adequately minimize risk of serious adverse health consequences or death from biological hazards in produce. However, as discussed in section IV.C.1.b., we have tentatively identified an approach based on outbreak data, and we further explore that option in that section. We welcome comment on this approach and ask that you provide data and factual information that would help us to further consider developing this or another appropriate commodity-specific approach.

1. Commodity-Specific Approaches

As noted above, there are multiple possible approaches that we could take with respect to produce. One of them is what we refer to as a ''commodity-specific approach'' in which this rule would apply only to those produce commodities or commodity groups that pose a relatively higher risk of foodborne illness. (We could also simply apply different or less stringent requirements to the relatively lower-risk commodities.) In theory, commodities might also be grouped into higher, moderate, or lower levels of risk with different levels of stringency applied to each. As discussed in section IV.A. above, we attempted to categorize commodities and commodity groups by risk in our Qualitative Assessment of Risk.

a. Relative Risk Considerations

To fully explore the viability of a commodity-specific approach, we reviewed the relative risk of different commodities using four such data sources: Outbreak data; Pathogen surveillance data; Commodity characteristics; and Market channels. Our analysis shows that each data source presents certain gaps that make it challenging to develop a commodity-specific approach that would adequately minimize risk of serious adverse health consequences or death. We explain our analysis below and request data and factual information on how we might address these gaps and further develop and consider a commodity-specific approach.

i. Outbreak Data and Commodity Risk: We reviewed FDA's data on produce-related outbreaks and considered categorizing commodities or commodity groups by risk based on documented association of specific produce commodities with specific outbreaks of human illness (Ref. 2). Using this approach, we could exempt certain commodities or commodity groups that had never been linked to human illnesses or were only rarely linked to human illness; this would allow us to reduce the costs of the rule with little or no reduction in calculated benefits. However, our QAR also leads us to tentatively conclude that past patterns of outbreaks by commodity have limitations which make it challenging to use as a key determining factor in establishing the scope of this proposed rule or how its provisions apply. We briefly discuss the reasons here (please refer to the QAR for more information).

Our QAR concluded that some produce types are repeatedly associated with reported foodborne illness, whereas other produce types are intermittently associated with reported foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. As such, five commodity groups (leafy greens, tomatoes, herbs, melons, and sprouts) together account for 77 percent of all produce-related outbreaks from 1996–2010 (Ref. 3). These commodity groups also account for 54 percent of produce-related illnesses and 56 percent of produce-related hospitalizations. Sprouts account for a quarter of the produce related outbreaks (26%), 15 percent of the illnesses, 9 percent of the hospitalizations, and one death.

As discussed in the QAR, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness. The food vehicle responsible for an outbreak is not identified in about half of all outbreaks. Identifying the vehicle of an outbreak in which the vehicle is contained in a multi-ingredient food (*e.g.,* salsa, salads) is particularly challenging. As our abilities to detect outbreaks and to identify food vehicles responsible for an outbreak improve, including refining our approach to outbreaks associated with multi-ingredient foods, it is likely that previously unrecognized outbreak vehicles will be identified. A further complication to use of outbreak data as an indication of commodity risk is that, until a food is identified as a vehicle in an outbreak, public health officials may not be likely to include questions about that commodity when investigating an outbreak, making the attribution of outbreaks to commodities with no outbreak history more difficult.

In addition, as discussed in the QAR, our data show that the patterns of outbreaks associated with produce commodities change over time. Some commodities have a continuing and repeated pattern of association with outbreaks, over multiple years, such as tomatoes and leafy greens (Ref. 2). On the other hand, occasionally a produce commodity is associated with an outbreak that had not been previously linked to foodborne illness. For example, prior to the 2008 Salmonella Saintpaul outbreak (Ref. 37), jalapeno and serrano peppers had not been identified as vehicles in a foodborne illness outbreak. Papayas had also not been associated with outbreaks, prior to an outbreak that occurred in 2011. Therefore, a regulatory approach that relied on a static list of commodities prepared solely from a history of outbreaks would not be able to prevent future outbreaks in commodities not previously associated with an outbreak.

If we adopted an approach that exempted commodities without a history of outbreaks, we would likely need to add commodities as future outbreaks occur. For example, we could adopt a ''moving window'' approach that would consider only outbreaks over a given time period. For example, we could consider only the outbreaks over the most recent five years at any given time. Using such an approach, produce commodities or commodity groups might move onto and off of the higher risk list over time based on changes in outbreak data. The advantage of such an approach could potentially be to

recognize and reward efforts by industry segments that implement changes in practices contributing to reduced outbreaks associated with their commodities, and provide an incentive for other industry segments to enhance the safety of their practices. However, the adoption of such practices by an industry segment does not change the risk posed by the commodity in the absence of such practices, such as when practices are not universally adopted or they are discontinued. In the absence of those practices, illness outbreaks may resume. For example, sprout associated outbreaks appeared to decline after release of our Sprout Guides in 1999 and, for three years (2005–2007), there were no reported outbreaks associated with sprouts, presumably because of improved practices during the production of sprouts (Ref. 3). However, outbreaks have recurred since that time period, possibly because practices have regressed to some extent or possibly because of the entry of new sprout growers who were not familiar with the voluntary recommendations in the Sprout Guides and had not adopted them. In late 2008, there was one sprout-associated Salmonella outbreak; in 2009, a Salmonella outbreak associated with sprouts resulted in more than 200 illnesses; and in 2010, there were 3 outbreaks associated with sprouts (Ref. 3). Further, as discussed in the QAR, some commodities (*e.g.,* leafy greens) are consistently associated with outbreaks while others (*e.g.,* grapes, jalapeno peppers) are only rarely associated with outbreaks. With a moving window approach those commodities that only intermittently are associated with outbreaks may cycle on and off the higher risk list, even though their risk may not have actually changed. For these reasons, we have tentatively concluded that a ''moving window'' approach for determining risk based on outbreak history is not viable.

Grouping commodities based on outbreak history also has challenges. Within a commodity group, contamination may have been associated with relatively few types of produce, such as cantaloupe and honeydew melons within the melon group, which includes multiple species, or more broadly, such as roma, red round, plum, and grape tomatoes within the tomato group, which consists of multiple varieties within a single species (Ref. 3).

Having considered that making exemptions solely based on outbreak data could significantly reduce the costs of the proposed rule with little or no reduction in calculated benefits, we have not selected this alternative, because we do not believe that the past history of outbreaks can be fully predictive of future outbreaks. Historically, outbreaks are sometimes linked to commodities that had no previous associated illnesses. If we were to develop a commodity-specific list of covered produce, we could add commodities to the list as more data became available. We request comment on whether this option would adequately minimize the risk of serious adverse health consequences or death and whether it would sufficiently move toward a prevention-based food safety system. We request comment on this determination and on the specific approaches we have outlined here. We are particularly interested in the marginal effects of adopting this approach: If we exempted commodities based on a history of outbreaks, what would the likely reductions in the costs of the rule be, and what would the likely increase in human illnesses be from this approach.

ii. Pathogen Surveillance Data and Commodity Risk: As an alternative to categorizing and regulating commodities based on outbreak history, we considered using data on levels and frequency of pathogen detection, such as by surveillance sampling assignments in specific produce commodities. As demonstrated in the QAR, this approach would also present a number of challenges. Of most importance, our contamination data are limited in that most sampling programs have focused on produce commodities that have an existing history of known outbreaks, providing little additional information about the risk presented by commodities that do not have such a history. Given the potential for system failure and sporadic contamination, it is probable that testing of other produce commodities may eventually lead to positive identification of contamination. For example, when we added cucumbers to our surveillance sampling program in 2009, we found a significant number of positive samples for Salmonella spp. although, in previous years, cucumbers had not been identified as the vehicle of a foodborne outbreak in FDA's database. We also found pathogens in and on produce commodities such as broccoli, culantro, rapini, and radicchio that have not been currently identified in outbreaks (Ref. 3). For this reason, we do not believe that pathogen surveillance data alone can provide sufficient information for a risk-based exemption from the proposed rule's provisions. We request comment on this determination.

iii. Commodity Characteristics and Commodity Risk: As an alternative to categorizing and regulating commodities based on outbreak history or surveillance data, we also considered using characteristics of produce commodities themselves, such as growth habit. In other words, if, for example, the risk of illnesses associated with tree fruit, were consistently lower than the risk of illness from commodities grown in the soil, such a distinction might provide the basis of an exemption. However, as demonstrated in the QAR, we found that it would be extremely difficult to make conclusions across commodity groups that are consistent with outbreak and surveillance data, in light of the diversity of commodities, practices, and conditions across operations.

Attempts to categorize produce by commodity characteristics is confounded by the outbreak data, which show no consistent pattern that can be matched to commodity characteristics such as growth habit. As discussed in the QAR, the characteristics of approximately 20 produce commodities associated with outbreaks are diverse and include:

- Crops generally grown without soil, such as sprouts;
- Crops where the harvestable portion grows in the ground, such as green onions;
- Row crops where the harvestable portion grows on or near the ground, such as lettuce, spinach, basil, parsley and cantaloupe;
- Crops where the harvestable portion grows above the ground, such as tomatoes and chili peppers, raspberries and blueberries; and
- Crops where the harvestable portion grows on trees, high above the ground, such as mangoes and almonds.

Moreover, as discussed in the QAR, even within what may be a reasonable set of commodities to group together, physical characteristics of the produce that could alter the potential for contamination do not always appear to do so. For example, within the melon group, cantaloupe has a netted rind, whereas honeydew has a smooth rind, seemingly making it less likely to harbor pathogens. However, both have been associated with outbreaks (Ref. 3).

In addition, multiple characteristics would have to be considered to create commodity groupings, making such an approach very complicated. For example, while growth characteristics, such as distance between the edible portion of the plant and the ground, may make a commodity less likely to become contaminated through certain routes, (*e.g.,* tree fruit may be less vulnerable to contamination from grazing animals), distance from the

ground does not necessarily provide an increased level of protection against other sources of contamination (*e.g.,* direct contact with a crop protection spray if the spray mix were made using contaminated water). Furthermore, once the produce commodity is removed from the growing area, it may lose any safety advantage it had in the field based on growth characteristics if it is exposed to routes of contamination such as poor worker hygiene practices, contaminated water, or insanitary food contact surfaces. As another example, mangoes are an example of a produce commodity that may be thought to present relatively low risk of foodborne illness, but for which poor water quality management during insect disinfestation hot water treatment and cooling as part of harvest, packing, and holding resulted in an outbreak (Ref. 38). Some physical characteristics of produce commodities (*e.g.,* netted rind of cantaloupe or large, rough surface area of some leafy greens) may increase the likelihood of contaminants being trapped and surviving long enough to cause illness, but as noted earlier, these characteristics do not necessarily determine whether contamination occurs or persists.

For the reasons described here, we have tentatively determined that such an approach cannot serve as the sole basis for a risk-based exemption from the proposed rule. We request comment on this determination and on whether there are known produce characteristics that could serve as a reliable and practicable indicator of contamination and illness risk. We seek comment on this issue and data to inform commodity categorization.

iv. Market Channel and Risk: We also considered whether different market channels might have an impact on the likelihood of contamination of produce and therefore whether use of certain market channels should be a factor in covering or regulating produce in this proposed rule. In particular, we considered whether there is a difference in the likelihood of contamination of produce that is sold directly to the consumer or end user (''direct market channels'') as compared to that of produce that is sold into other commercial channels. We are not aware of any data that would enable us to compare the likelihood of contamination in these two situations. We tentatively conclude that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, although the number of opportunities for contamination during packing and holding may be greater for produce in other commercial channels as compared to produce in direct market channels if there are greater numbers of touch points and handlers in these channels than there are in direct market channels. We seek comment on this tentative conclusion.

Section 419(f) of the FD&C Act provides a qualified exemption from this proposed rule for many farms selling directly to consumers or other ''qualified end users,'' and as a result, many farms that primarily use direct market channels will not be subject to the requirements of this proposed rule (with qualifications provided by the statute). Because the statutory qualified exemption addresses market channels as a possible risk factor, and because we identified no data that would allow us to otherwise use market channels as a factor in covering and regulating produce under this proposed rule, we tentatively conclude that we should not otherwise use market channels as a basis of risk categorization in this proposed rule. We seek comment on this tentative conclusion.

b. Considering an Appropriate Commodity-Specific Approach

In the previous section, IV.C.1.a, we discuss four different relative risk considerations that might be used to develop an appropriate commodity-specific approach. Each has a set of challenges, as discussed above. Of the four, outbreak data provide the most direct representation of public health burden, even considering the confines associated with these data. In this section we further explore how outbreak data might be used to identify commodity groups or specific commodities to cover in this proposed rule.

One possible commodity-specific approach would be to cover those commodity groups that have been associated with outbreaks. Commodity groups ''associated with outbreaks'' could be identified as, for example, commodity groups associated with one or more outbreaks during a set period of time. The remaining commodity groups could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. A commodity-specific approach that covers the commodity groups associated with outbreaks would target the commodity groups that present the greatest public health burden. However, as discussed above in section IV.C.1.a., there are various drawbacks with using outbreak data in this way. For example, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness.

Another possible commodity-specific approach that attempts to account for the drawbacks of the above approach would be to cover *all* of the commodities that have been identified as associated with an outbreak at any time. Produce commodities that have not been identified as associated with an outbreak could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. This option would address more than the percent of known outbreaks addressed by the above approach in that it would address all known outbreaks. This approach would also significantly reduce the costs of the proposed rule by exempting produce categories that have never been associated with human illness. As discussed above, however, outbreaks have been associated with commodities without an illness history. Although we would expect to use additional data to update any list we might develop of commodities subject to the provisions of the rule, we would expect that this approach would not minimize the risk of occurrence of some number of additional outbreaks and illnesses.

We have discussed limitations with each of the above methods of creating a risk-based exemption from the rule. We could also combine two or more of the approaches used above to create a more holistic picture of risk. For example, we might combine a history of outbreak data with the growing characteristics of a commodity or class of commodity. Such an approach could potentially exempt additional commodities that pose minimal or no risk (in addition to those we already considered in the proposed approach: Those specified as rarely consumed raw, and those that are receive commercial processing that adequately reduces the presence of microorganisms of public health significance). If there were individual commodities or classes of commodities that have not been linked to human illness and we had reason to believe that they were unlikely to be linked to human illness in the future, we would consider exempting these commodities or classes of commodities from some or all provisions of the rule. This would reduce the cost of the rule without significantly reducing the calculated benefits of the rule. However, we have not been able to fully develop an approach that might combine a history of outbreak data with the growing characteristics of a commodity or class

of commodities to create risk-based exemptions from the rule and, thus, minimize the risk of serious adverse health consequences or death. We seek comment on this issue. Is there information in the QAR that could be used to develop such a system of risk-based exemptions? Are there commodity characteristics or growth conditions that could be used as a basis to develop such a system? Do the proposed provisions for variances (see section V.P. below) adequately address this issue?

We ask for comment on all of the above approaches, and we especially ask for comment on the likely marginal effects of the different risk-based exemptions. If we adopted one of the approaches above, what would the likely reductions in the costs of the proposed rule be, and what would the likely increases in human illnesses be (using our proposed rule as a baseline). We also ask for comment on whether any of the above approaches would be sufficiently protective of the public health.

c. Need for additional data and information

We seek comment on our analysis and considerations related to considering an appropriate commodity-specific approach that would adequately minimize risk of serious adverse health consequences or death from biological hazards associated with produce. We also request comment on whether and how different relative risk considerations, including outbreak data, pathogen surveillance data, commodity characteristics and/or market channels, could be used to develop a commodity-specific approach, and data and factual information that would address the drawbacks that are discussed in this section IV.C. that may be accounted for in such an approach. Specifically,

- Are there specific commodities or categories of commodities that should be excluded from the scope of the rule, based on data related to their relative risk considerations? (Note that under our proposed integrated approach, we propose to exempt certain commodities, including a specified list of produce that is rarely consumed raw, and produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance; see section V.A.2.a. of this rule.)
  - For example, the QAR ranked certain produce commodities, such as bananas and coconuts, as lower risk for illness, in part because such commodities are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity. Should such commodities be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements?
  - Certain commodities are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because such commodities have fewer potential routes of contamination and/or lower potential for contamination. In addition, some commodities are not known to have been associated with outbreaks. Some commodities (for example, pears, grapefruit, oranges, and lemons) meet both of these criteria, considering the rankings and outbreak data used in the QAR. Should commodities that meet both of these criteria be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements? How should the rule address the changing nature of outbreak data over time?
  - How should the agency account for uncovered commodities in considering a commodity-specific approach that relies on outbreak data?
- Are there pathogen surveillance data from sampling programs focusing on produce commodities that have no history of known outbreaks that would be useful in considering a commodity-specific approach?
- Can commodity characteristics be used as a basis to consider a commodity-specific approach? While the outbreak data show no consistent pattern that can be matched to commodity characteristics such as growth habit, our QAR shows that produce commodities that are ranked as higher risk of illness and those ranked as lower risk of illness do share some of the same characteristics. A further refinement of our assessment might be helpful in developing a commodity-specific approach based on commodity characteristics. Considering the qualitative nature of our assessment, are there quantitative data sets available that would enable a further refinement of our assessment?
- Are produce in both direct market channels and other commercial channels subject to the same routes of contamination? Is the number of opportunities for contamination during packing and holding greater for produce in other commercial channels as compared to produce in direct market channels? If yes, is this due to greater numbers of touch points and handlers in these channels than there are in direct market channels, or to other factors?
- Should market channels be used as a basis for risk categorization? If so, how? Is there a need to consider market channels in risk categorization, considering that the statutory qualified exemption already addresses market channels as a possible risk factor?
- Are other data or information available that would otherwise be useful in considering a commodity-specific approach?

2. Integrated Approach, as Proposed

As discussed in section IV.A. above, our QAR indicates that some produce types are repeatedly associated with reported foodborne illness whereas other produce types are intermittently associated with foodborne illness. Still other produce commodities have not been associated with reported foodborne illness. Likely factors contributing to the likelihood of contamination, exposure, and illness include: Agricultural practices used during growing, harvesting, and postharvest; physical characteristics of the crop; consumer and retail handling practices (such as cooking and peeling); and rates of consumption. However, use of poor agricultural practices could lead to contamination and illness, even where the potential for contamination is relatively low.

Therefore, we tentatively conclude that an integrated approach that focuses on the likelihood of contamination of produce posed by the agricultural practices applied to the crop, while exempting the lowest-risk produce, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. We tentatively conclude that controls should be tailored, taking into account the analysis done by the farm in certain areas, to the potential routes of contamination that each commodity presents based on the agricultural practices employed, and the characteristics of the commodity and the environmental conditions under which it is grown.

Based on our QAR, we are able to identify certain conditions under which produce commodities constitute very low to no risk with respect to biological hazards. We tentatively conclude that, under these conditions, science-based minimum standards to minimize the risk of serious adverse health consequences or death from biological hazards in produce are not warranted. As described in the QAR, such conditions include produce that receives commercial processing that

adequately reduces the presence of microorganisms of public health significance (proposed § 112.2(b)); and produce commodities that are rarely consumed raw (proposed § 112.2(a)(1)). In each of these cases the produce can be expected to receive commercial processing or other treatments that significantly minimize the risk of serious adverse health consequences or death from biological hazards associated with such produce.

In addition, as discussed in section V.A. of this document, FDA proposes in § 112.4 to apply this regulation only to businesses with an average annual monetary value of food sold during the previous three-year period of more than $25,000 on a rolling basis, based on a tentative conclusion that businesses with $25,000 or less in sales do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated. Accordingly, imposing the proposed requirements on these businesses would have little measurable public health impact. In addition to these exclusions proposed by FDA, section 419(f) of the FD&C Act provides a qualified exemption for certain farms, which FDA proposes to implement in proposed §§ 112.5 and 112.6, and subpart R, as discussed in sections V.A. and V.R. of this document.

For produce commodities that would be covered within the scope of this rule (*i.e.,* ''covered produce'' as defined in proposed § 112.3), we are proposing to establish science-based minimum standards to minimize the risk of serious adverse health consequences or death. Given our current understanding of existing microbiological hazards and current data limitations, as described in our QAR, we have determined that a regulatory approach that addresses the potential likelihood of contamination posed by procedures, processes, and practices employed in the growing, harvesting, packing, and holding of produce commodities will be more effective and appropriate than an approach based on the individual commodities' physical characteristics, known record of contamination, or known outbreak history. The only commodity-specific requirements proposed in this rule are those designated for sprouts, which have unique growing procedures (*i.e.,* warm, moist nutrient-rich environment for an extended period of time that supports pathogen growth in addition to sprouting) and, therefore, present a unique risk profile (Ref. 16.Ref. 2). For this reason, and as discussed in section V.M. of this document, we tentatively conclude that a specific set of safety standards (proposed subpart M) for this produce commodity is warranted.

The requirements of the proposed regulation would be based on identified routes of contamination and the associated practices that affect the likelihood that produce becomes contaminated: Agricultural practices that are more likely to contaminate produce would require more stringent measures to ensure that the likelihood of contamination is sufficiently minimized. For example, as discussed in section V.E. of this document, we are proposing the most stringent standards for water that is used in direct contact with the harvestable portion of covered produce during or after harvest activities (when there is little further opportunity for pathogen die off) and in certain other uses that present significant safety risk for the safety of the produce (such as irrigation of sprouts); less stringent standards for water that directly contacts the harvestable portion of covered produce (other than sprouts) during growing activities (when the opportunity for pathogen die off is greater); and no requirements when water is used during growing, but does not contact the harvestable portion of covered produce (other than sprouts). Similarly, we are proposing to prohibit the use on covered produce of biological soil amendments that present the greatest likelihood of pathogen contamination, *i.e.,* untreated human waste (Ref. 39). Untreated manure or other untreated biological soil amendments of animal origin, which are less likely to be contaminated with human pathogens than human waste, but are relatively likely to be contaminated (Ref. 35. Ref. 36. Ref. 37), would be allowed, subject to stringent requirements; manure or other biological soil amendments of animal origin that have been properly composted to reduce the level of pathogens contained therein would be subject to less stringent requirements; and certain chemically or physically treated biological soil amendments of animal origin that receive more robust treatments to eliminate pathogens would be subject to the least stringent requirements.

In addition, we are proposing to include other measures that would be broadly applicable (*e.g.,* personnel qualifications and training requirements in proposed subpart C, health and hygiene requirements in proposed subpart D; requirements for equipment, tools, buildings, and sanitation in proposed subpart L) and the proposed standards for these are consistent for all covered growing, harvesting, packing, and holding operations.

We tentatively conclude that the appropriate way to minimize the risk of serious adverse health consequences or death is to require all covered farms to comply with the standards in this proposed rule with regard to all but the lowest risk produce. Identifying the higher-risk agricultural practices and setting standards in which the stringency of the requirement tracks the risk of the chosen practices is appropriate from a public health risk mitigation standpoint and would also provide an incentive for farmers to move to lower-risk practices where such options are available. We also expect that our proposed approach is more workable for row crop farmers who may grow multiple produce commodities than it would be if we were to assign different requirements to specific commodities based on the risk of foodborne illness associated with those commodities. In these types of operations, many agricultural practices and agricultural inputs (such as water sources and distribution systems, soil amendments and their application methods) tend to be farm-specific and, thus, relatively consistent across produce commodities on a given farm. Requiring different measures from row to row based on the produce commodity in that row would likely pose a considerable burden on such farms. Setting standards that enable such farms to apply consistent measures to multiple crops is consistent with the statutory provision in section 418(c)(1)(D) of the FD&C Act that directs the agency to ''acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.''

D. Framework of the Rule

In developing a framework for this proposed rule we considered various models used in proposed and final FDA regulations, including those applied in: (1) The existing Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food regulation (current 21 CFR part 110; ''Food CGMP regulation''); (2) the Production, Storage, and Transportation of Shell Eggs regulation (21 CFR part 118; ''Shell Egg Regulation''); (3) the Hazard Analysis and Critical Control Point (HACCP) Systems (''juice HACCP'') regulation (21 CFR part 120); and (4) the Fish and Fishery Products (''seafood HACCP'') regulation (21 CFR part 123). None of these regulations applies to fruits and vegetables at the point at which we propose to regulate such food by this regulation (during growing, harvesting,

packing, and holding on farms), but as models they are instructive.

Generally, the Food CGMP Regulation sets out mandatory, broad, generally-applicable practices and conditions that are required to be met, and the criteria and definitions in that part are applicable in determining whether the food is adulterated (1) within the meaning of section 402(a)(3) of the act, in that the food has been manufactured under such conditions that it is unfit for food, or (2) within the meaning of section 402(a)(4) of the act, in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in that part are also applicable in determining whether a food violates section 361 of the Public Health Service Act. In some instances where the appropriate measures are universal and well recognized, the cGMP requirements are prescriptive (*e.g.,* the requirement to remove unsecured jewelry at § 110.10(a)(4), the requirement that each freezer and cold storage compartment be fitted with a temperature indicating thermometer, temperature measuring device or temperature recording device at § 110.40(e)). However, more commonly, because of the diversity of operations subject to the regulation and the desire to provide flexibility for operators to put in place measures that are best suited to the specifics of their operation, the cGMP rule sets out more general requirements (*e.g.,* the requirement that persons working in direct contact with food conform to hygienic practices to the extent necessary to protect against contamination of the food at § 110.10(b), the requirement that food that can support the rapid growth of undesirable microorganisms be held in a manner that prevents the food from becoming adulterated at § 110.80(b)(3)). Many provisions of the Shell Egg Regulation also take a similar approach to the Food CGMP Regulation.

The Juice HACCP and Seafood HACCP Regulations set out mandatory frameworks through which entities subject to those regulations assess the hazards that are reasonably likely to occur in their products and processes and design tailored controls to prevent or eliminate them or reduce them to an acceptable level. These regulations require the development of a plan, based on the assessment of hazards, which includes monitoring procedures, corrective action procedures, verification procedures, and recordkeeping procedures. The plan also includes the identification of the critical control points (CCPs) where the controls must be applied and critical limits, which are the set points for the process that must be met to ensure product safety.

The Food CGMP Regulation and the Shell Egg Regulation do not use the structure applied in the other regulations identified here to ensure that the conditions and practices are keeping hazards in check as anticipated (through hazard analysis, establishment of critical control points, monitoring, corrective actions, verification, and recordkeeping in all applicable contexts). The Food CGMP Regulation preceded the HACCP regulations and is generally thought of as a pre-requisite or foundation to those regulations. That is, it is generally recognized that HACCP-type regulations must build on the foundation of a good manufacturing practice (GMP)-type regulation in order to further reduce the risk of illness or injury to consumers associated with contaminated produce (Ref. 40 Ref. 41).

In developing the framework for this proposed rule, we considered the following: (1) The produce farming community is very diverse, including very small and large farms, some with significant expertise in the area of food safety and others with minimal knowledge in the area, some located in the U.S. and some abroad; (2) there is a broad range of crops and agricultural practices employed by the produce farming community, such that a measure for addressing an on-farm route of contamination for one produce commodity in one region may not be practical or effective for another on-farm route of contamination, produce commodity or region; (3) this proposed rule is the first effort by FDA to regulate the produce farming community—the produce farming community does not have the history of regulatory interaction with FDA and the same experience with food safety regulations as does the food manufacturing industry; (4) the adequacy of some measures to control specific known or reasonably foreseeable hazards affecting produce is well established, while others are poorly studied, suggesting that future research may identify alternative measures that may be more effective and/or efficient; and (5) some on-farm routes of contamination occur in a relatively controlled environment (*e.g.,* a fully or partially enclosed building), while others occur in an outdoor environment that may be beyond the control of the farm (*e.g.,* an open field), affecting the ability of the farm to take measures that minimize the likelihood of contamination.

Given these considerations, and the need to tailor the proposed requirements to specific on-farm routes of contamination (as discussed in section IV.C of this document), we propose an integrated approach that draws on our past experiences in the regulations discussed above. In some cases, we propose standards that are very similar to those contained in the Food CGMP Regulation, especially where the routes of contamination are well-understood and appropriate measures are well-established and generally applicable across covered produce commodities (*e.g.,* personnel qualifications, training, health, and hygiene; harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation). We rely on this approach where possible, in part, because we tentatively conclude that compliance would be more suitable with this regulatory framework (given the diversity of the industry with respect to size, agricultural practices, and knowledge of food safety) than would be the case with a more complex framework such as one that also required an individual written plan.

In other cases, we have proposed specific numerical standards against which the effectiveness of a farm's measures would be compared and actions taken to bring the operation into conformance with the standards, as necessary (*e.g.,* proposed standards for agricultural water in subpart E; biological soil amendments of animal origin in subpart F; sprout environmental testing and spent sprout irrigation water testing in subpart M). We rely on such a numerical standards approach where the effectiveness of individual measures (*e.g.,* protection of agricultural water sources from contamination, establishment of application intervals for certain soil amendments, and chemical disinfection treatment of seeds before sprouting) is not complete or fully known and/or because much of what affects the on-farm route of contamination is outside the control of the farm (*e.g.,* the quality of a particular surface water source). In some of these cases (*e.g.,* composting of biological soil amendments of animal origin in proposed § 112.54) we have provided measures that are well established to meet the numerical standard under a wide range of conditions, while also recognizing that other measures, if properly validated, may also be suitable (see proposed § 112.12, discussed in section V.B. of this document). Our proposed use of numerical standards is similar to the

requirement for egg testing in the Shell Egg Regulation.

In still other cases, we have proposed a standard that requires the farm to inspect or monitor an on-farm route of contamination and take appropriate measures if conditions warrant. We rely on such a monitoring approach where the diversity of conditions that can be expected relative to an on-farm route of contamination is very high and it would be impractical and unduly restrictive to set out a standard that specifies the appropriate measures for each possible circumstance (*e.g.,* requirements for monitoring for animal intrusion in proposed § 112.83, requirement for inspection of agricultural water system in proposed § 112.42). In addition, we propose this approach in instances where further research is needed to fully understand the effectiveness of measures to mitigate the risk of serious adverse health consequences or death. Our proposed use of inspection and monitoring followed by appropriate corrective action is similar to the requirement to monitor for rodent activity and take corrective action on egg farms in the Shell Egg Regulation (§ 118.4).

Finally, in still other cases, we propose a standard that requires the farm to develop a written plan, committing itself to specific measures (*e.g.,* sprout environmental testing and spent sprout irrigation water testing). We propose the use of written plans where the details of the measures to be taken are more than can be reasonably expected to be retained in memory, especially where the details may change over time and a historical record of the evolution of the measures is important for the operator to assess whether further changes to the measures are needed (*e.g.,* changes or rotation in the sampling sites for sprout environmental testing). Such plans are also important for the efficient enforcement of the standard as they serve as a clear commitment on the part of the operator of the farm to a particular course of action, against which their actual performance can be judged by the regulator. Our proposed use of written plans in these specific instances is similar to the requirement for a written Salmonella Enteritidis prevention plan on egg farms in the Shell Egg Regulation (§ 118.4).

We performed a quantitative risk assessment to estimate the predicted effectiveness of some of the provisions of the proposed regulation with respect to one example commodity and one example pathogen (Ref. 42). This quantitative risk assessment evaluated the combination of fresh-cut lettuce, enterohemorrhagic *E. coli* (EHEC), and irrigation water (with and without proposed measures in place), and concluded that a number of variables may influence the predicted EHEC illnesses associated with fresh-cut lettuce, as defined by the model scenarios that included contamination from irrigation water and other environmental sources on the farm, and changes in the contamination during the product life cycle from farm to consumption. The quantitative risk assessment document is currently being peer reviewed and changes can be reasonably anticipated based on the peer review. The peer review plan is available online at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.* We will consider peer reviewers' and public comments in finalizing the quantitative risk assessment and this proposed rule.

This rulemaking is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism.'' (§ 418(b)(2) of the FD&C Act). FDA plans to implement section 103 of FSMA regarding such hazards in a separate rulemaking in the future. FDA tentatively concludes that intentional hazards likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we request comment on whether we should include standards related to preventing economically motivated intentional adulteration of produce in this rule. Is economically motivated adulteration of produce reasonably likely to occur and, if so, by what mechanisms may potential hazards be intentionally introduced in produce for economic reasons? If such adulteration is reasonably likely to occur, what standards should FDA consider for preventing such adulteration?

E. Records

We are proposing to require that farms keep records as a component of the above described standards, under certain, limited circumstances. In determining those circumstances in which records are necessary, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) ''with special attention to minimizing'' the recordkeeping burden on the business and collection of information as defined in that act.

Records are useful for keeping track of detailed information over a period of time. Records can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful for investigators during inspections to determine compliance with requirements (*e.g.,* by FDA investigators to determine compliance with requirements that would be established by this rule, or by a third party auditor that a farm or retailer may voluntarily engage under a business arrangement between the farm and the retailer). We propose to require records in instances where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records; where identification of a pattern of problems is important to minimizing the likelihood of contamination; and where maintenance of detailed information is needed by the operator in order to minimize the risk of contamination and demonstrate their compliance.

F. Farm-Specific Food Safety Plans

Each farm has a unique combination of size, climate, crops grown, current and previous use of its own land and nearby land, sources of agricultural water, growing, harvesting, packing, and holding practices, animal grazing, potential for domestic and wild animals to enter growing or packing areas, and sewage or septic system. Relevant documents on produce safety, such as our GAPs Guide (Ref. 10), industry CSGs for melons, tomatoes, leafy greens, and green onions (Ref. 43. Ref. 44. Ref. 45. Ref. 46), the CA and AZ LGMA (Ref. 31. Ref. 32), the AFDO Model Code of Produce Safety (Ref. 20), the Codex Guide (Ref. 47), and Industry Harmonized GAPs (Ref. 48. Ref. 49) recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation. In addition, many of these documents explicitly recommend that a farm conduct an assessment of its growing environment and may specify when assessments should be done (*e.g.,* before planting, during production, and immediately prior to harvest) to identify potential food safety hazards in light of its particular commodities, practices and conditions (Ref. 43. Ref. 44. Ref. 45. Ref. 46. Ref. 40. Ref. 47).

Several of these documents further recommend that a farm use the findings of its assessment to help establish a plan to control potential hazards (Ref. 43. Ref. 46. Ref. 48. Ref. 45. Ref. 49. Ref. 28. Ref. 18)(Ref. 50. Ref. 51). For example, the introduction to the AFDO Model Code notes that a food safety plan should be commensurate with the size and complexity of an operation and the inherent risks of the commodities

grown, along with site specific practices and conditions. The purpose of a food safety plan is to establish measures designed to prevent the introduction of known or reasonably foreseeable food safety hazards into or onto produce in light of the crops, practices, and conditions at the physical location of the farm and would include, for example, measures applicable to an individual farm for agricultural water, animal grazing, and any specific hazards identified in the recommended operational assessment. The FDA draft CSGs recommend developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, field, facility, and vehicle cleaning and sanitation, and employee training programs. A number of comments to the 2010 FR notice maintained that the most effective approach to produce safety would be one that incorporates food safety plans developed at the operational level. Conversely, another group of comments questioned the need for some industry segments, such as small farms or growers of ''low risk'' commodities to develop or implement food safety plans. The above-mentioned documents provide guidance or recommendations for operators to consider and, as such, do not represent requirements that must be met. We recognize that requiring covered farms to conduct a hazard analysis and develop a food safety plan at the level required in our juice and seafood HACCP regulations, or prescribed by section 418 of FSMA for food manufacturing/processing facilities, may not be feasible. We also recognize that, at this time, only limited tools are available to help with the development of on-farm food safety plans.

Also as noted above, this proposed rule is the first effort by FDA to regulate the produce farming community. We have tentatively concluded, in part based on the statutory direction in section 419 to establish ''minimum science-based standards,'' and in recognition of the direction to pay special attention to minimizing recordkeeping burden and collection of information, that the most appropriate approach for this proposed rule is to establish standards of the type described in section D above. We are not proposing to require farms to conduct operational assessments or to develop food safety plans akin to similar requirements for facilities subject to section 418 of FSMA or our juice HACCP or seafood HACCP regulations. We acknowledge that operational assessments and food safety plans have a prominent place in many public and private produce guidance documents, as discussed above.

The importance of tailoring what you do at an individual operation to your commodities, practices and conditions is commonly accepted, and an operational assessment and food safety plan could be valuable tools for farms to select and implement those recommendations which are appropriate for their circumstances. While we are not proposing to require farms to conduct an operational assessment or develop a food safety plan, we do recommend that farms do so, because this could help farms be more effective in protecting the safety of their produce.

Further, we request comment on whether we should require that some or all covered farms perform operational assessments and/or develop a food safety plan, and if only some, what criteria should be used to separate those to whom the requirement would apply from those to whom it would not.

G. Foreign Farms

The proposed rule would apply to foreign farms that meet the criteria to be covered farms and that grow, harvest, pack, or hold covered produce for import into the United States. This is protective of public health, as foreign farms have been implicated in foodborne illness outbreaks associated with contaminated produce consumed in the United States (Ref. 3). This is also consistent with the requirements of section 419 of the FD&C Act, which clearly contemplates that the rule issued under that authority will apply to foreign farms. This is apparent in sections 419(c)(1)(F) and (c)(2), which provide for a variance process in which states or foreign countries from which food is imported into the US may request variances from FDA. Foreign countries would not be eligible to request variances from this rule if Congress did not intend the rule to apply to farms in foreign countries.

H. Consistency With Codex Guidelines

In developing our proposed approach, we considered the recommendations of relevant Codex guidelines, specifically, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53–2003) (the Codex Code). Many of the provisions proposed in this rule are parallel to or consistent with the recommendations in the Codex Code. For example, like our proposed approach of focusing on biological hazards, the Codex Code (while intended to help control microbial, chemical and physical hazards associated with production of fresh fruits and vegetables) pays particular attention to minimizing microbial hazards. It concentrates on microbial hazards and addresses physical and chemical hazards only in so far as they relate to good agricultural and manufacturing practices. The Codex Code recommends measures applicable to all stages of the production of fresh fruits and vegetables, from primary production to packing, with a particular emphasis on those intended to be consumed raw (Section 2.1 of the Codex Code). In proposed § 112.2(a)(1), we propose to exempt a specified list of produce that is rarely consumed raw from the scope of this rule. Similarly, for those commodities not cooked before consumption, the Codex Code recommends a set of broadly applicable minimum standards, with risk-based adjustments.

With respect to agricultural water, the Codex Code recommends the assessment of agricultural water for suitability for use; special attention to irrigation water that is directly applied to edible portion, especially close to harvest; and use of clean water for initial stages followed by potable water for later stages during and after harvest, including cooling (Section 3.2.1.1 of the Codex Code). Many of the proposed provisions described in section V.E. of this document are consistent with these recommendations.

As another example, the Codex Code recommends that personnel follow health and hygiene requirements and that toilet and hand washing and drying facilities be provided during and after harvest, which are reflected in the proposed provisions described in section V.D. of this document. In addition, the proposed provisions described in section V.L. of this document and the Codex Code both recognize the importance of proper design, construction, maintenance and cleaning of buildings and equipment in ensuring produce safety.

Moreover, the Codex Code recommends that ''manure, biosolids and other natural fertilizers which are untreated or partially treated may be used only if appropriate corrective actions are being adopted to reduce microbial contaminants, such as maximizing the time between application and harvest of fresh fruits and vegetables'' (Section 3.2.1.2 of the Codex Code). The recommendation to consider maximizing time between application of untreated amendments and harvest is reflected in proposed provisions described in section V.F. of this document, in particular proposed § 112.56, which stipulates application

intervals for different biological soil amendments of animal origin.

The Codex Code also recommends that ''existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh produce growing areas from animals. As far as possible, domestic and wild animal should be excluded from the area'' (Section 3.1 of the Codex Code). We believe that the proposed provisions in § 112.82, which requires an adequate waiting period between grazing by working animals and harvesting when under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, and § 112.83, which requires monitoring for wild animal intrusion and assessment of safety of harvest where significant intrusion is evident if under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, are consistent with (though not identical to) these Codex recommendations.

Furthermore, the proposed requirements related to the maintenance of records (described in section V.O. of this document) are in concert with the Codex documentation and records recommendations for growers and packers, which states: ''Growers should keep current all relevant information on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation practices, use of agricultural chemicals, water quality data, pest control and cleaning schedules for indoor establishments, premises, facilities, equipment and containers. Packers should keep current all information concerning each lot such as information on incoming materials (*e.g.* information from growers, lot numbers), data on the quality of processing water, pest control programmes, cooling and storage temperatures, chemicals used in postharvest treatments, and cleaning schedules for premises, facilities, equipment and containers, etc.'' (Section 5.7 of the Codex Code). In the discussion throughout section V of this document, we point out where the proposed provisions are consistent with these and other recommendations of the Codex Code.

I. Product Testing as a Strategy To Control Pathogens

We considered requiring microbiological product testing either routinely or under specific conditions as a strategy to minimize known or reasonably foreseeable hazards. While not widely adopted, product testing is being used by some in the produce industry. Some produce buyers for retail distributors require routine microbial testing of product as a condition of sale in their purchasing specifications (Ref. 52). Individual fresh-cut produce companies began product testing in response to the 2006 *E. coli* O157:H7 outbreak associated with bagged fresh spinach (Ref. 53). At least one company is reported to use product testing to verify the efficacy of good agricultural practices programs and to prevent contaminated product lots from entering commerce (Ref. 52). The California Leafy Greens Marketing Agreement requires crop testing for *E. coli* O157:H7 and *Salmonella* spp. whenever a crop has been directly contacted with water that exceeds the agreements' acceptance criteria for generic *E. coli* (Ref. 31).

Product testing, especially microbiological testing, for process control purposes presents several challenges. Pathogen prevalence in produce as a result of contamination events that occur during growing, harvesting, packing, or holding on farms are generally temporally intermittent, non-homogeneous in a lot or a field, and at low concentrations (Ref. 54). Therefore, unlike some processed foods that may consist of batches of homogeneous material (*e.g.,* bulk flour, milk, juice), produce are best thought of as individual units, and while a positive test result for one unit does raise concern about the rest of the lot or the field subject to the same conditions, procedures, processes, and practices, any contamination present in one unit may not have necessarily spread to other units. In addition, it is generally recognized that negative product test results do not necessarily indicate the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. 55. Ref. 56). Sampling plans intended to ensure detection of contamination with a reasonable assurance of success in produce lots or fields can be cost-prohibitive, and may not be effective for use in produce. For example, for any given contamination rate, the probability of detecting *Salmonella* increases with the number of samples tested and it is not feasible to identify low levels of contamination in an individual lot. For example, when 30 samples in a lot are tested, the probability of detecting *Salmonella* is 1 percent when the contamination rate is 1 in 3000, 26 percent when the contamination rate is 1 in 100, and 96 percent when the contamination rate is 1 in 10 (Ref. 57). Both industry and FDA survey data indicate that contamination rates in produce (melons, greens, tomatoes), while variable, are typically very low (Ref. 58. Ref. 59). In addition, microbial testing can only detect the pathogens that the analytical procedures are designed to detect. Testing instead for indicator organisms may be a viable option, but is not without challenges, as discussed in section V.E.2. of this document.

Another factor affecting the utility of product testing for pathogens as a control measure is that FDA recommends, and it is generally industry practice, to hold any batch of product from which samples are taken for testing to prevent the need for a recall should the test results demonstrate the presence of a pathogen. With a highly perishable product as is the case for most produce, storing product during such analyses would significantly reduce the shelf-life of the product. For these reasons, we tentatively conclude that product testing would be impracticable as a component of science-based minimum standards proposed in this rule except as set forth in proposed subpart M under certain circumstances for sprouts.

J. Effective Dates

We are proposing that the effective date of this rule would be 60 days after the date of publication of the final rule in the **Federal Register** with staggered compliance dates. The effective date is the date that provisions in the rule affect the current CFR.

An effective date of 60 days after date of publication of the final rule in the **Federal Register** would be consistent with the effective dates in recent FDA rules directed to food safety. See, *e.g.,* **Federal Register** of July 9, 2009 (74 FR 33029 at 33030), establishing an effective date of September 8, 2009, for a final rule for the prevention of Salmonella Enteritidis in shell eggs during production, storage, and transportation; and **Federal Register** of June 25, 2007 (72 FR 34751 at 34752), establishing an effective date of August 24, 2007, for a final rule for current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements.

K. Compliance Dates

We are proposing that the compliance dates for entities subject to the rule would be based on the size of a farm and the effective date of the requirement, with additional flexibility

for compliance with proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)).

The compliance date for very small businesses (those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $250,000, as defined in proposed § 112.3(b)(1)) would be four years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for very small businesses would not be in conflict with the requirement in section 419(b)(3)(B) of the FD&C Act for the regulations promulgated under section 419 to apply to very small businesses ''after the date that is 2 years after the effective date of the final regulation. * * *'' because this requirement specifies that the regulations shall apply after, not on, the date that is 2 years after the effective date. To provide additional flexibility to small businesses, we would provide two more years for very small businesses to comply with the rule than is required under section 419(b)(3)(B). Providing an extended compliance period to very small businesses as a means of providing additional flexibility is consistent with our approach to compliance dates in recent rules directed to food safety. (See, *e.g.,* 74 FR 33029 at 33034 and 72 FR 34751 at 34752.)

The compliance date for small businesses (those subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food sold during the previous three-year period is no more than $500,000, as defined in proposed § 112.3(b)(2)) would be three years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for small businesses would not be in conflict with the requirement in section 419(b)(3)(A) of the FD&C Act for the regulations promulgated under section 419 to apply to small businesses ''after the date that is 1 year after the effective date of the final regulation. * * *'' because this requirement specifies that the regulations shall apply after, not on, the date that is 1 year after the effective date. To provide additional flexibility to small businesses, we would provide two more years than is required under section 419(b)(3)(A). Providing an extended compliance period to small businesses as a means of providing additional flexibility is consistent with our approach to compliance dates in recent rules directed to food safety. (See, *e.g.,* 74 FR 33029 at 33034 and 72 FR 34751 at 34752.)

The compliance date for all other farms subject to the rule would be two years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below).

The compliance dates for water quality requirements in proposed § 112.44 and related provisions in §§ 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would be two years beyond the compliance date for the rest of the final rule applicable to the farm based on its size. We recognize that farms may need additional time to cope with implementation of the water quality testing, monitoring, and related record-keeping provisions. This additional compliance period would also be expected to permit farms to consider identifying alternatives to the standard in proposed § 112.44(b) and developing adequate scientific data or information necessary to support a conclusion that the alternative would provide the same level of public health protection as the standard that would be established in this part, and would not increase the likelihood that the covered produce will be adulterated under section 402 of the FD&C Act, in light of the farm's covered produce, practices, and conditions. The extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would then be six years from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms subject to the rule.

The compliance dates would apply to all farms subject to the rule, including those farms that satisfy the requirements in proposed § 112.5 for an exemption from most requirements of the rule, because such farms have modified requirements (proposed § 112.6) to which they would be subject on the relevant compliance date.

We seek comment on these proposed implementation periods. In addition, given that activities related to produce production, harvesting, packing, and holding may be affected by the produce growing season, we seek comment on whether these compliance dates sufficiently address any issues related to the seasonal nature of produce-related activities.

V. The Proposal

A. Subpart A—General Provisions

As proposed, subpart A contains provisions that establish the scope of, and definitions applicable to, this regulation, and identifies who is subject to the requirements of this part. This subpart also describes the proposed modified requirements and procedures governing qualified exemptions from this rule.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to the general scope of this proposed rule. Some comments requested that tree crops be exempt from this regulation. For example, an apple grower asserted that apples are not as susceptible to *E. coli* and other pathogens as are lettuce and tomatoes, and therefore they should not be subject to the same controls and restrictions. Additionally, one grower stated that citrus fruits should be exempt because citrus fruits have not been identified to be the source of an incident of food-borne illness, a majority of such produce does not touch the ground, citrus fruit are washed during the packing process, and the peel is rarely consumed raw. Several comments from produce associations requested removal of watermelons from the ''melon'' category, stating that they should have their own category since they have a different risk profile from other melons. In addition, comments from several tree nut growers stated that some tree nut commodities should have less rigorous requirements or be exempt.

As we explained in Section IV.C, we tentatively concluded that an approach that considers both the risk associated with the commodity and that associated with the agricultural practices applied to the crop under the conditions in which it is grown, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. Under this approach, we considered available information on outbreaks and contamination as well as existing evidence on characteristics of the commodity (such as whether the commodity grows on trees or has a smooth rind). This evidence informed the proposed requirements, but we have tentatively concluded that limiting the scope of this rule based on outbreak data or on the levels of frequency of pathogen detection alone would not adequately address the risk of serious adverse health consequences or death. Therefore, as discussed in section

V.A.2.a. of this document, we are proposing to cover apples, citrus fruits, watermelons, and tree nuts in this proposed rule. Because the scope and stringency of the regulatory requirements depends in several cases on the types of practices employed within operations, producers of different commodities who use different practices will not be subject to all of the same controls and restrictions. We seek comment on our proposed approach. Because our regulatory approach does not depend on categorizing commodities based on risk profiles, we do not see the need to distinguish among fruits, including watermelons, on this basis. We do note, however, that in proposed § 112.1(b)(1) we have listed watermelons separately from other melons. While we propose to cover tree nuts that do not meet the criteria we propose for ''rarely consumed raw'' (see section V.A.2.a) in this proposed rule, such as walnuts and almonds, we recognize that many of these tree nuts receive commercial processing to adequately reduce pathogens and, thus, may be eligible for an exemption under proposed § 112.2(b) (discussed in section V.A.2.a. of this document). Our main food safety concerns relevant to on-farm growing, harvesting, packing, and holding of tree nuts pertain to those tree nuts that would be sold raw and untreated. We request comments on our treatment of tree nuts in this proposal.

We also received comments regarding various activities performed on produce in relation to the scope of this proposed rule. One comment stated that ''processing'' should not refer to rinsing heads of lettuce or bunches of greens before they are packed for market, but rather should be defined specifically to include other processes that appear to involve additional risk to the consumer. Some comments suggested that no grower should be exempt from these food safety regulations, whereas another stakeholder stated that the produce safety standards must be very clear as to what constitutes produce processing versus produce preparation for market acceptance and that Part 110 should be reserved for situations where extensive commingling, cutting, washing and bagging of produce are practiced. Finally, a comment suggested that growers who deliver produce to the consumer within 24–30 hours should be exempt from this regulation. As discussed in section III.F. of this document and further in section V.A.2.b.i below, this proposed rule would apply to activities of farms and farm mixed-type facilities that are within the definition of ''farm'' proposed here. A farm or farm mixed-type facility that washes its own covered produce would be harvesting within the farm definition and therefore that activity would be covered by this proposed rule unless another exemption applied. However, a farm mixed-type facility that washes covered produce not grown on that farm or another farm under the same ownership for distribution into commerce would be engaging in an activity outside the farm definition (*i.e.,* a manufacturing/processing activity). Such activities would not be subject to this rule but instead would be subject to section 418 of the FD&C Act.

As discussed in section I of this document and the QAR, produce is vulnerable to contamination by pathogens, which can occur at various points during growing, harvesting, packing, and holding. Although contamination usually occurs in low doses, even low doses of some of these harmful pathogens can result in human illness or death (Ref. 60). Thus, if produce is contaminated with a pathogen, there is a reasonable possibility that the amount of the pathogen present will be enough to cause serious adverse health consequences or death to a consumer even without an extended time period before consumption for the pathogen to grow and multiply. In addition, even in cases where the delivery time may not exceed 24–30 hours, consumers and other recipients may store produce (in a refrigerator or otherwise) thereafter and not consume it immediately, allowing additional time for pathogen growth. Therefore, FDA tentatively concludes it would not be appropriate to exempt any farms from this proposed rule based on the speed of their deliveries to the consumer.

2. Proposed Requirements

a. Food Covered by This Rule

This proposal is applicable to certain farm activities performed on certain produce for use as human food. Section 105 of FSMA does not specify whether the rulemaking conducted under that section should apply to human food, animal food, or both. The general rulemaking requirements in 419(a)(1)(A), (b)(1), and (c)(1)(A) authorize FDA to establish standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. FDA tentatively concludes that the risk posed to animals, and to humans from contact with animals or consumption of animals as food, by farm practices in producing and harvesting fruits and vegetables does not merit imposition of new regulatory requirements at this time. Therefore, this proposal is limited to produce for use as human food. Produce that is intended for use as animal food would not be subject to the requirements of this rule. This is reflected in the title of the proposed rule (''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'') and its proposed location in Chapter I, Subchapter B of Title 21, Code of Federal Regulations (''Food for Human Consumption'').

As proposed, § 112.1 establishes the scope of food that is subject to this rule. Under proposed § 112.1(a), food that meets the definition of produce in § 112.3(c) and that is a raw agricultural commodity (RAC) as defined in section 201(r) of the FD&C act, would be covered by part 112, unless it is excluded by § 112.2. Section 201(r) defines ''raw agricultural commodity'' as any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.'' This includes produce RACs grown domestically and produce RACs that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. As discussed in section III and IV of this document, FDA tentatively concludes that proposed § 112.1(a) is consistent with section 419(a)(1)(A) of the FD&C Act, which directs us to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

We propose to establish a definition of ''produce'' in proposed § 112.3(c) (see section V.A.2.b.iii. of this document) that would be relevant to the use of that term in proposed § 112.1. ''Produce'' would mean any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and would include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. Within the definition of ''produce,'' we would further define ''fruit'' and ''vegetable'' to reflect the common meanings of those terms.

We would define a fruit as the edible reproductive body of a seed plant or tree

nut (such as apple, orange and almond), such that fruit would mean the harvestable or harvested part of a plant developed from a flower. This is consistent with the common meaning of the term ''fruit,'' as demonstrated by the Merriam-Webster Dictionary definition of ''fruit'' to mean, in relevant part ''the usually edible reproductive body of a seed plant; especially: One having a sweet pulp associated with the seed * * * a succulent plant part (as the petioles of a rhubarb plant) used chiefly in a dessert or sweet course * * * a product of fertilization in a plant with its modified envelopes or appendages; specifically: The ripened ovary of a seed plant and its contents * * *'' (Ref. 61).

We would define a vegetable as the edible part of an herbaceous plant (such as cabbage and potato) or fleshy fruiting body of a fungus (such as white button and shiitake) grown for an edible part, such that vegetable would mean the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil and cilantro).

This is consistent with the common meaning of the term ''vegetable,'' as demonstrated by the Merriam-Webster Dictionary definition of ''vegetable'' to mean, in relevant part, ''a usually herbaceous plant (as the cabbage, bean, or potato) grown for an edible part that is usually eaten as part of a meal; also: Such an edible part * * *'' (Ref. 61).

We are proposing to specify in the definition of produce that it includes mushrooms, sprouts, peanuts, tree nuts and herbs, to leave no doubt about the status of these foods. Taxonomically, a mushroom is a fungus (Ref. 62). For regulatory purposes in the United States, however, mushrooms have generally been treated as vegetables. Mushrooms are classified as vegetables by USDA AMS under the Perishable Agricultural Commodities Act (7 U.S.C. 499a–499t) (PACA) (Ref. 63), using a definition stating in relevant part that ''fresh fruits and fresh vegetables'' means ''all produce in fresh form generally considered as perishable fruits and vegetables * * *'' (21 CFR 46.2(u)). The USDA 2010 Dietary Guidelines for Americans also include mushrooms in the ''vegetable'' food group (Ref. 64). In addition, the produce industry appears to recognize mushrooms as vegetables, as demonstrated by various industry documents (Ref. 65. Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of mushrooms are generally similar to those for other produce (Ref. 67). Accordingly, we tentatively conclude that it is reasonable to include mushrooms in the proposed definition of ''vegetable.''

Sprouts meet the definition of ''vegetable'' above from the Merriam-Webster Dictionary (Ref. 61). In addition, sprouts are classified as vegetables by USDA AMS under PACA (Ref. 63). The USDA 2010 Dietary Guidelines for Americans also include ''bean sprouts'' in the ''vegetable'' food group (Ref. 64). In addition, the produce industry appears to recognize sprouts as vegetables, as demonstrated by various industry documents (Ref. 68). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of sprouts are generally similar to those for other produce, but with additional controls necessary due to the unique risks presented by sprouts (Ref. 160. Ref. 161) (see section V.M of this document). Accordingly, we tentatively conclude that it is reasonable to include sprouts in the proposed definition of ''vegetable.'' Herbs meet the definition of ''vegetable'' above from the Merriam-Webster Dictionary (Ref. 61). Herbs are generally consumed in combination with other foods (for example, in salads or as garnishes) rather than consumed as distinct servings, but they nonetheless satisfy the dictionary definition of ''vegetable.'' In addition, USDA considers herbs to be covered commodities under PACA, such that they are classified as ''herbs'' but fall within the broader category of ''fresh fruits and fresh vegetables'' (Ref. 63). In addition, the produce industry appears to recognize herbs as vegetables, as demonstrated by various industry documents (Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of herbs are generally similar to those for other produce(Ref. 13. Ref. 50). Accordingly, we tentatively conclude that it is reasonable to include herbs in the proposed definition of ''vegetable.''

Peanuts and tree nuts both meet the definition of ''fruit'' above from the Merriam-Webster Dictionary (Ref. 61). The Merriam-Webster Dictionary defines ''peanut,'' in relevant part, as ''a low-branching widely cultivated annual herb * * * of the legume family with showy yellow flowers having a peduncle which elongates and bends into the soil where the ovary ripens into a pod containing one to three oily edible seeds * * *,'' and ''nut,'' in relevant part, as ''a hard-shelled dry fruit or seed with a separable rind or shell and interior kernel * * *'' (Ref. 61). In addition, the produce industry appears to recognize peanuts and tree nuts as produce, as demonstrated by various industry documents (Ref. 65. Ref. 66). Moreover, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of peanuts and tree nuts are generally similar to those for other produce (Ref. 69. Ref. 70). Specifically, peanuts and tree nuts share the significant hazard of pathogens with other covered produce. To a significant extent, this hazard is eliminated during manufacturing/processing operations, such as roasting, by facilities subject to section 418 of the FD&C Act, rather than through measures taken by farms subject to this regulation. However, as discussed in section V.A.2.a below, peanuts meet our proposed criteria for ''rarely consumed raw'' and therefore would be exempt from this proposed rule. Tree nuts that do not meet the criteria for ''rarely consumed raw'' would also be exempt from this proposed regulation if you establish and keep documentation that demonstrates that the recipient of the produce performs commercial processing in accordance with proposed § 112.2(b)(1). For tree nuts that remain subject to the proposed rule, the kinds of measures necessary to minimize the risk of known or reasonably foreseeable biological hazards are the same as those in subparts A through O of this proposed rule (*e.g.,* control of soil amendments, agricultural water, worker hygiene). Accordingly, we conclude it is reasonable to include peanuts and tree nuts in the proposed definition of produce as a ''fruit.'' We recognize that peanuts and tree nuts are not covered commodities under PACA ((Ref. 63. Ref. 71) and that the USDA 2010 Dietary Guidelines for Americans consider nuts a ''protein food'' rather than as part of the ''fruits and vegetables'' group for the purpose of providing dietary advice (Ref. 72); however, in light of the treatment of peanuts and tree nuts as produce in common usage and in the produce industry, and the commonality of on-farm hazards and controls for peanuts, tree nuts, and other produce (Ref. 70. Ref. 69), we tentatively conclude that it is reasonable to include peanuts and tree nuts in the proposed definition of produce as ''fruits.''

We propose to specify in the definition of ''produce'' that the term would not include food grains, meaning the small, hard fruits or seeds of arable

crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains would include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybean. Our proposed definition of ''food grains'' is consistent with the common meaning of the term ''grain'' when used in the context of food, as demonstrated by the Merriam-Webster Dictionary definition of ''grain'' to mean, in relevant part, ''a seed or fruit of a cereal grass * * * the seeds or fruits of various food plants including the cereal grasses and in commercial and statutory usage other plants (as the soybean) * * * plants producing grain * * *'' (Ref. 61). In addition, the industry appears to recognize grains as a separate commodity group from produce, as demonstrated by various industry documents regarding ''produce'' and ''fruits and vegetables'' that do not include grains (Ref. 65. Ref. 66). Grains are not covered commodities under PACA (Ref. 63). The USDA 2010 Dietary Guidelines for Americans treat grains as a separate food group from the ''fruits and vegetables'' food group (Ref. 73). In addition, the hazards and controls relevant to minimizing serious adverse health consequences or death during the growing, harvesting, packing, and holding of grains are significantly different from those relevant to fruits and vegetables (Ref. 74). Specifically, the hazards of concern in grains are primarily chemical hazards such as mycotoxins and pesticides, rather than biological hazards (which, as discussed in section IV.B. of this document, are the only hazards we currently propose to address in this rule, as they are the most significant hazards affecting covered produce), because grains are milled and/or cooked such that pathogens that may be present are reduced to a level where they are unlikely to present a risk to public health for most products. Accordingly, we tentatively conclude that it is reasonable to exclude grains from the definition of ''produce.''

Proposed § 112.1(b)(1) lists specific examples of produce covered by this rule. Such covered produce would include almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress and watermelon.

The list of fruits and vegetables provided in proposed § 112.1(b)(1) is not an exhaustive list of produce covered by this rule. This section is intended simply to provide examples of produce commonly consumed in the United States that would be included within the scope of this regulation. The absence of a specific fruit or vegetable from this list does not indicate that it is not covered, except where the specific fruit or vegetable is exempted from the regulation by § 112.2(a)(1). We request comment on the examples of fruits and vegetables listed in 112.1(b)(1).

Proposed § 112.1(b)(2) would clarify that mixes of intact fruits and vegetables (such as fruit baskets) are also covered by this rule. Proposed § 112.1(b)(2) is consistent with section 419(a)(1)(A) of the FD&C Act, which includes mixes or categories of fruits and vegetable RACs as part of the rulemaking requirement we are implementing through this proposed rule.

As proposed, § 112.2(a) identifies three types of produce not covered by this rule. First, proposed § 112.2(a)(1) provides an exclusion for produce that is rarely consumed raw. FDA proposes to establish the following exhaustive list of specific fruits and vegetables that would be exempt under this provision: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams. Because these listed fruits and vegetables are almost always consumed only after being cooked, which is a kill-step that adequately reduces the presence of microorganisms of public health significance, we propose that these listed produce be excluded from the requirements of this rule. Studies have shown that the numbers of microorganisms of public health significance (such as *Listeria monocytogenes, Salmonella,* shiga toxin-producing *E. coli*) are significantly reduced in produce by a variety of relatively moderate heat treatments (Ref. 75. Ref. 76. Ref. 77. Ref. 78). Therefore, we tentatively conclude that the cooking that the produce listed in § 112.2(a)(1) receive before they are consumed, whether commercially or by the consumer, would be sufficient to minimize the risk of serious adverse health consequences or death.

We note that all produce commodities are and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether they are included within the scope of this proposed rule.

We developed this list in proposed § 112.2(a)(1) of produce that rarely is consumed raw by analyzing consumption data on selected produce commodities using data available from the National Health and Nutrition Examination Survey (NHANES) and other resources (Ref. 79). We looked at the percentage of the population consuming the produce commodity in fresh form as well as the percentage of eating occasions on which the produce commodity is eaten uncooked (Ref. 79. Ref. 80). As explained further in a memo to the record, we found that artichokes, asparagus, beets, bok choy, brussels sprouts, cranberries, eggplant, figs, ginger root, lima beans, okra, plantains, potatoes, rhubarb, sweet corn, sweet potatoes, turnips, and yams are eaten uncooked by less than 0.1% of the U.S. population and are consumed uncooked on less than 0.1% of eating occasions (Ref. 79). Other commodities, including black-eyed peas, chick-peas, collard greens, crabapples, kale, kidney beans, lentils, parsnips, peanuts, pinto beans, pumpkin, rutabaga, sugarbeet, taro, water chestnut, and winter squash (which includes both acorn and butternut squash) are included in the NHANES data set but their categories of reported consumption do not include ''uncooked,'' indicating that they are not consumed uncooked in any measurable quantity (Ref. 79). Still other commodities on the list, namely, arrowhead and arrowroot, are not identified in the NHANES data set as being eaten in the United States in any form, uncooked or otherwise (Ref. 79). Other references indicated that those commodities are typically consumed

cooked (Ref. 63. Ref. 82). We request comment on the proposed criteria used for identifying the commodities that are rarely consumed raw. Further, we request comment on additional commodities that should be considered for inclusion in the list in 112.2(a)(1). As noted above, we analyzed consumption data on selected produce commodities to generate this list. We acknowledge that there may be additional commodities that would meet these criteria that we did not analyze. Also, we anticipate that, in the case of some commodities, the consumption rates in the United States may be too low for the NHANES data and other data sources used in our analysis to support a conclusion that the commodity is rarely consumed raw using our proposed criteria. We request comment on additional sources of information and/or criteria that should be applied in such cases.

We also request comment on the inclusion of commodities that our analysis indicates are rarely consumed raw, but may not be prepared in a manner that would kill microbial contaminants, should they be present on the food. For example, we have included asparagus, bok choy, and cranberries in the list of commodities that will be exempt from the requirements of this rule in proposed § 112.2(a)(1) because the NHANES data indicated that these commodities are consumed uncooked by less than 0.1% of the U.S. population and are consumed uncooked on less than 0.1% of eating occasions (Ref. 79). However, we are concerned that the method of food preparation that these commodities may be subjected (for example, stir frying bok choy) to prior to consumption may not constitute a kill-step that adequately reduces the presence of microorganisms of public health significance. We request comment on our tentative conclusions about these commodities and others proposed for exclusion in § 112.2(a)(1).

Second, § 112.2(a)(2) proposes to exempt produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership. With respect to the exemption for personal consumption, section 419(g) of the FD&C Act specifically exempts food produced by an individual for personal consumption from this rulemaking, and proposed § 112.2(a)(2) implements this exclusion. With respect to the exclusion for produce for consumption on the farm or another farm under the same ownership, such activities are within the definition of farm that we propose here, and would therefore be subject to this rule without an exemption. To the extent that there is any difference between produce ''for personal consumption'' and produce ''consumed on the farm or another farm under the same ownership,'' FDA proposes to exclude produce for either type of consumption from this proposed rule.

Third, § 112.2(a)(3) proposes to exclude produce that is not a raw agricultural commodity from this proposed rule. For example, this would exclude ''fresh-cut'' produce, which is subject to current part 110 and to section 418 of the FD&C Act as applicable (Ref. 83). This is consistent with section 419(a)(1)(A) of the FD&C Act, which directs FDA to ''establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables * * * that are raw agricultural commodities * * *.'' This is also consistent with the application of this rule to activities within the farm definition. In section V.A.2.b.i of this document, we discuss how we considered how the activities of farms relate to the concept of a RAC and tentatively concluded that the farm definition and related definitions in this proposed rule should be revised based on the concept that RACs are the essential products of farms. Accordingly, the definitions proposed here (for the terms farm, mixed-type facility, harvesting, manufacturing/processing, packing, and holding) reflect the tentative conclusion that activities involving RACs that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.'' This is the case even if the same activities off-farm would be considered to be ''manufacturing/processing'' because those activities involve ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' This special classification of on-farm activities, however, should only apply to RACs because only RACs, not processed foods, are the essential products of farms. For all of these reasons, RACs are a logical and appropriate focus for these produce safety standards.

In addition to these three exemptions mentioned above, under the conditions specified in § 112.2(b), we propose to allow covered produce which receives commercial processing that adequately reduces the presence of microorganisms of public health significance to be eligible for an exemption from the requirements of this part (except for subparts A, Q, and O). Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, part 114, or part 120; treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products. As discussed in section IV.C. of this document, FDA tentatively concludes that such commercial processing significantly minimizes the risk of serious adverse health consequences or death associated with biological hazards for such produce, such that the produce can be considered to be low risk and the imposition of the requirements in this proposed rule is not warranted. We note that such produce is and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether it is included within the scope of this proposed rule.

As proposed, to qualify for the § 112.2(b) exemption, proposed § 112.2(b)(2) would require you to establish and keep documentation of the identity of the recipient of the covered produce that performs the commercial processing in accordance with the requirements of proposed subpart O. FDA tentatively concludes that such records are necessary for the efficient enforcement of the FD&C Act. Without such records, FDA would have no way to assess whether farms are complying with the terms of this exemption. In addition, proposed § 112.2(b)(3) would clarify that the requirements of subparts A and Q apply to such produce because subpart A includes relevant provisions such as the scope of this rule and definitions, and Q contains provisions relating to compliance and enforcement.

It is important to note that any of the exemptions in proposed § 112.2 are only applicable to the produce specified in the exemption. In other words, a covered farm may not rely on these exemptions for all of its covered produce simply because a subset of that produce is rarely consumed raw; is for personal or on-farm consumption; is not a RAC; or will receive the requisite commercial processing; in those instances, only the subset that meets the relevant exemption criteria would be exempt from this proposed rule. For

example, if you own or operate a farm that produces both tomatoes that will be processed into tomato paste, and tomatoes that will not receive any commercial processing to adequately reduce pathogens, and you do not qualify for any other exemption, you would be subject to the rule when you grow, harvest, pack or hold those tomatoes that will not be processed to adequately reduce pathogens. Likewise, if you produce both artichokes and lettuce, you would be subject to the rule when you grow, harvest, pack or hold lettuce, but you would not be subject to the rule when you grow, harvest, pack, or hold artichokes.

We request comment on proposed §§ 112.1 and 112.2, including the specific examples of produce that would be covered by the rule; the list of produce that would not be covered by the rule because it is rarely consumed raw; and the proposed exemption for produce that receives commercial processing, including the types of processing that should qualify for this exemption.

b. Definitions

Proposed § 112.3 would establish the definitions of terms for purposes of part 112. To the extent possible, the new definitions proposed in § 112.3 are consistent with the common meanings of these terms as well as the definitions of the terms in other food safety regulations (see, *e.g.,* current § 110.3 and § 111.3) and other applicable sources. As proposed in § 112.3(a), to provide clarity and consistency, the definitions and interpretations of terms in section 201 of the FD&C Act will apply to such terms when used in part 112.

i. Definitions of ''Farm,'' ''Mixed-Type Facility,'' and Related Activities

We are proposing to establish an inter-related series of definitions in this proposed rule that, collectively, would address several issues related to the scope of establishments (namely, ''farms'') that would be subject to the rule. These inter-related definitions include two definitions for types of establishments (*i.e.,* ''farm'' and ''mixed-type facility'') and five definitions for types of activities (*i.e.,* ''harvesting,'' ''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing'') conducted on farms and mixed-type facilities.

These proposed definitions are based on definitions already established in our regulations (*e.g.,* in § 1.227 in the regulations for Registration of Food Facilities, established under section 415 of the FD&C Act; hereinafter the section 415 registration regulations). However, the definitions that we are proposing for the purpose of the produce safety rule have some differences relative to the current definitions established in the section 415 registration regulations. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of the produce safety proposed rule.

In developing these proposed definitions, we considered how the activities of farms relate to the statutory concepts of ''raw agricultural commodity'' and ''processed food.'' The FD&C Act defines ''raw agricultural commodity'' and ''processed food'' in relation to each other, and identifies certain activities that transform a raw agricultural commodity (RAC) into a processed food and others that do not. Section 201(r) of the FD&C Act (21 U.S.C. 321(r)) defines ''raw agricultural commodity'' to mean ''any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.'' Section 201(gg) of the FD&C Act (21 U.S.C. 321(gg)) defines ''processed food'' to mean ''any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.'' In addition, section 201(q)(1)(B)(i)(II) of the FD&C Act (which defines pesticide chemicals) contains the following language regarding activities that do not transform a RAC into a processed food: ''the treatment [with pesticide chemicals] is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).''

The status of a food as a RAC or processed food is relevant for many different purposes under the FD&C Act, including section 419(a)(1)(A) of the FD&C Act, which authorizes FDA to establish minimum science-based standards applicable to certain fruits and vegetables that are RACs. For example, under 403(w) of the FD&C Act (21 U.S.C. 343(w)), labeling requirements related to major food allergens apply to processed foods but do not apply to RACs. Under sections 201(q), 403(k), 403(l), and 408 of the FD&C Act (21 U.S.C. 321(q), 343(k), 343(l), and 346a), the status of a food as a RAC has an impact on the manner in which pesticide chemicals and their residues are regulated. FSMA created more provisions in the FD&C Act and elsewhere that take status as a RAC or processed food into account, including section 417(f) of the FD&C Act (21 U.S.C. 350f(f)), establishing notification requirements for reportable foods that do not apply to fruits and vegetables that are RACs; section 418(m) of the FD&C Act, which authorizes FDA to exempt or modify the requirements for compliance under section 418 with respect to facilities that are solely engaged in the storage of RACs other than fruits and vegetables intended for further distribution or processing; and section 204(d)(6)(D) of FSMA (21 U.S.C. 2223(d)(6)(D)), which contains special provisions for commingled RACs applicable to FDA's authority under section 204 of FSMA to establish additional recordkeeping requirements for high risk foods.

The term ''raw agricultural commodity'' and similar terms also appear in other Federal statutes. While these statutes are not implemented or enforced by FDA and do not directly impact the interpretation of the definitions in sections 201(r) and 201(gg) of the FD&C Act, they do provide some suggestions about what ''raw agricultural commodity'' and related concepts can mean in various circumstances. For example, the Secretary of Transportation may prescribe commercial motor vehicle safety standards under 49 U.S.C. 31136, but the Motor Carrier Safety Improvement Act of 1999 (Pub. L. 106–159, title II, Sec. 229, Dec. 9, 1999), as added and amended by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109–59, title IV, Sec. 4115, 4130, Aug. 10, 2005), provided an exemption from maximum driving or on-duty times for drivers transporting ''agricultural commodities'' or farm supplies within specific areas during planting and harvest periods. In that circumstance, ''agricultural commodity'' is defined as ''any agricultural commodity, non-processed food, feed, fiber, or livestock * * * and insects'' (49 U.S.C. 31136 note). Another example is 19 U.S.C. 1677(4)(E), which provides for certain circumstances in which producers or growers of raw agricultural products may be considered part of the industry producing processed foods made from the raw agricultural product for the purposes of customs duties and tariffs related to such processed foods. In that circumstance, ''raw agricultural product'' is defined as ''any farm or fishery product'' (19 U.S.C. 1677(4)(E)). These statutes are informative in that they suggest that the ''raw agricultural commodity'' concept describes and

signifies the products of farms in their natural states, or, in other words, that which a farm exists to produce on a basic level.

Because the status of a food as a RAC or processed food is of great importance in defining the jurisdiction of FDA and the U.S. Environmental Protection Agency (EPA) over antimicrobial substances, FDA and EPA have developed guidance regarding whether or not various activities transform RACs into processed foods. FDA and EPA jointly issued a legal and policy interpretation of the agencies' jurisdiction under the FD&C Act over antimicrobial substances used in or on food (hereinafter the ''1998 Joint EPA/FDA Policy Interpretation'') (63 FR 54532, October 9, 1998). In 1999, FDA issued guidance addressing several of the issues discussed in the 1998 Joint EPA/FDA Policy Interpretation. (See Guidance for Industry: Antimicrobial Food Additives, July 1999 (hereinafter ''Antimicrobial Guidance'') (Ref. 84)). Table 1 summarizes activities that cause food RACs to become processed foods and activities that do not change the status of a food RAC, as set out in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance.

TABLE 1—THE EFFECT OF ACTIVITIES ON RACS THAT ARE FOODS

Activities that change a RAC into a processed food	Activities that do not change the status of a RAC
Canning	Application of pesticides (including by washing, waxing, fumigation, or packing).
Chopping	Coloring.
Cooking	Drying for the purpose of storage or transportation.
Cutting	Hydro-cooling.
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form.
Freezing	Packing.
Grinding	Refrigeration.
Homogenization	Removal of leaves, stems, and husks.
Irradiation	Shelling of nuts.
Milling	Washing.
Pasteurization	Waxing.
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant.
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering.	
Slicing.	
Activities that alter the general state of the commodity.	

In developing the proposed definitions, we also considered the definition of ''manufacturing/processing'' that FDA established in § 1.227. Under § 1.227(b)(6), ''manufacturing/processing'' means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. The summary in Table 1 demonstrates that the activities that transform a RAC into a processed food (and are sometimes therefore referred to as ''processing'' in the context of a food's status as a RAC or processed food) are not coextensive with the definition of ''manufacturing/processing'' that FDA established in § 1.227(b)(6) for the purposes of the section 415 registration regulations. The definition of ''Manufacturing/processing'' in that regulation includes most food-handling activities because it is satisfied by any degree of ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' In contrast, transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity (Ref. 3, section 7 and 63 FR 54532 at 54541), sometimes referred to as transformation of the RAC into a new or distinct commodity (61 FR 2386 at 2388). Because the activities that transform a RAC into a processed food are not coextensive with the definition of ''manufacturing/processing'' in § 1.227(b)(6), a given activity may be manufacturing/processing under the current definition in § 1.227(b)(6) without transforming a RAC into a processed food. Examples of such activities include coloring, washing, and waxing.

The current section 415 registration regulations demonstrate that some activities may be classified differently on farms and off farms. For example, ''washing'' is an example of manufacturing/processing under the definition of that term in § 1.227(b)(6). However, ''washing'' produce is identified as part of harvesting under the farm definition in § 1.227(b)(3), so washing on farms is harvesting rather than manufacturing/processing under the Section 415 registration regulations. To date, we have not articulated organizing principles explaining these differences.

In this document, we are tentatively articulating five organizing principles (summarized in Table 2 below) to explain the basis for the proposed definitions that would classify activities on-farm and off-farm for the purpose of this proposed rule. In the near future, we plan to address how we will coordinate the definitions in the section 415 registration regulations with the definitions we are proposing for the purpose of this proposed rule.

First Organizing Principle. The statutes we describe above, and previous interpretations of the concepts of RACs and processed food as set forth in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance, lead FDA to tentatively conclude that the basic purpose of farms is to produce RACs and that RACs are the essential products of farms.

Second Organizing Principle. Our second organizing principle is that activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.'' This is because

the basic purpose of farms is to produce RACs (principle 1). This is the case even if the same activities off-farm would be considered to be manufacturing/processing, because those activities involve ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.''

Third Organizing Principle. Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food. This is because principle 2 (*i.e.,* the special classification of on-farm activities) should only apply to RACs. A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm.

Fourth Organizing Principle. Principle 2 (*i.e.,* the special classification of on-farm activities) should only apply to RACs grown or raised on the farm itself or on other farms under the same ownership because the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce. (For the purposes of this discussion, we refer to RACs grown or raised on a farm or another farm under the same ownership as a farm's ''own RACs,'' in contrast to RACs grown on a farm under different ownership, which we refer to as ''others' RACs.'') Activities that farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce. In general, when a farm opts to perform activities outside the farm definition, the establishment's activities that are within the farm definition should be classified as manufacturing/processing, packing, or holding in the same manner as for a farm that does not perform activities outside the farm definition, but the activities that are outside the farm definition should be classified in the same manner as for an off-farm food establishment.

Fifth Organizing Principle. Manufacturing/processing, packing, or holding food— whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition because otherwise farms could not feed people and animals on the farm without being considered to have engaged in activities outside the farm definition.

TABLE 2—SUMMARY OF ORGANIZING PRINCIPLES REGARDING CLASSIFICATION OF ACTIVITIES ON-FARM AND OFF-FARM

Number	Organizing principle
1	The basic purpose of farms is to produce RACs and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.''
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
5	Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

We are proposing to include definitions for two types of establishments (*i.e.,* ''farm'' and ''mixed-type facility'') and five types of activities (*i.e.,* ''harvesting,'' ''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing''), to reflect the organizing principles articulated immediately above and to clarify how those definitions apply to specific activities depending on where the activities take place, the food used in the activities, where the food comes from, and where the food is consumed. We discuss these proposed definitions in this section because they are inter-related; however, we propose that they appear in § 112.3(c) in alphabetical order with the other definitions discussed in section V.A.2.b.iii of this document below.

We are proposing to define ''farm'' to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. The proposed definition of ''farm'' is based on the definition already established in § 1.227(b) in the section 415 registration regulations, except that it does not include the statement ''Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.'' The description of harvesting activities is included in a separate proposed definition of ''harvesting'' and thus would be redundant in the proposed definition of ''farm.''

We are proposing to define ''Mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. This term and its definition were initially developed in the preamble to the proposed rule on food facility registration (68 FR 5378 at 5381) and in the interim final rule on food facility registration (68 FR 58894 at 58906–7, 58914, 58934–8). The proposed definition would also provide, as an example of such a facility, a definition of a ''farm mixed-type facility.'' A ''farm mixed-type facility'' would be defined as an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. This definition is important to include in this rule because the activities of farm mixed-type facilities that are within the definition of ''farm'' are potentially subject to this rule, as provided in proposed § 112.4. FDA would apply this proposed rule only to the ''farm'' portion of these establishments' activities, and not to the ''non-farm'' portion of their activities (which would be subject to section 418 of the FD&C Act and therefore not subject to this proposed rule, consistent with section 419(h) of the FD&C Act). Put another way, farms and the ''farm'' portion of

the activities of farm mixed-type facilities would be subject to this proposed rule as applicable. For simplicity, FDA proposes to reference these activities collectively in proposed § 112.4(a) as one aspect of what makes an entity a ''covered farm'' and then to refer only to ''covered farms'' throughout the proposed rule. Thus, references to ''farms'' and ''covered farms'' throughout this proposed rule should be understood to include the portion of a farm mixed-type facility's activities that are within the farm definition.

We are proposing to define the term ''Harvesting'' to apply to farms and farm mixed-type facilities and be defined as activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting would be limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting would not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership would be listed as examples of harvesting. This proposed definition would include the same examples of ''harvesting'' that are currently part of the farm definition in § 1.227(b)(3) (washing, trimming of outer leaves, and cooling) and would add other examples to help clarify the scope of the definition of harvesting. ''Harvesting'' is a category of activities that is only applicable to farms and farm mixed-type facilities. Activities that would be ''harvesting'' when performed on a farm on the farm's own RACs would be classified differently under other circumstances, such as at a processing facility that is not on a farm, or when performed by a farm on others' RACs. For example, at an off-farm facility that packs tomatoes, washing the tomatoes after they are received would not be ''harvesting'' because it is not being performed on the farm that produced the tomatoes (or another farm under the same ownership). Instead, washing tomatoes at the off-farm packing facility would be ''manufacturing,'' because it involves preparing, treating, modifying, or manipulating food.

We are proposing to define ''Holding'' to mean the storage of food. The proposed definition would state that, for farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just storage of food would be classified as ''holding'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, fumigating or otherwise treating a farm's own RACs against pests for the purpose of safe and effective storage would be ''holding'' under this proposed definition. However, fumigating or otherwise treating food against pests under other circumstances (such as off-farm or by a farm handling others' RACs) would not be ''holding'' food because it is not storage of food, which would remain the definition of holding applicable to most circumstances.

We are proposing to define ''Manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that, for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. Under this proposed definition, the expanded definitions of ''packing'' and ''holding,'' and the extra category ''harvesting,'' would apply to activities performed by farms and farm mixed-type facilities on their own RACs. These expanded and extra categories would not apply off-farm or to foods other than a farm's own RACs or a farm mixed-type facility's own RACs. Thus, some activities that would otherwise be manufacturing/processing would instead be defined as packing, holding, or harvesting by virtue of being performed by a farm or farm mixed-type facility on its own RACs. Accordingly, these activities would not be manufacturing/processing because they would already be classified into the expanded definitions of packing or holding, or into the extra category of harvesting.

We are proposing to define ''Packaging'' to mean (when used as a verb) placing food into a container that directly contacts the food and that the consumer receives. We are proposing to use the same definition of ''packaging'' as is currently established in § 1.227.

We are proposing to define ''Packing'' to mean placing food into a container other than packaging the food. The proposed definition would also state that, for farms and farm mixed-type facilities, packing would also include activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just placing food into a container other than packaging would be classified as ''packing'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, packaging (placing food into a container that directly contacts the food and that the consumer receives) a farm's own RACs would be ''packing'' under this definition because farms traditionally do this to provide greater protection for fragile RACs than would be possible if the RACs were placed in containers other than the consumer container, and because this activity does not transform a RAC into a processed food. However, packaging food under other circumstances would not be ''packing'' food because packaging is explicitly excluded from the definition of packing applicable to most circumstances (placing food into a container other than packaging). Other examples of activities that could be packing when performed by a farm or a farm mixed-type facility on its own RACs include packaging or packing a mix of RACs together (*e.g.,* in a bag containing three different colored bell peppers, or a box of mixed produce for a community sponsored agriculture program farm share); coating RACs with wax, oil, or resin coatings used for the purposes of storage or transport; placing stickers on RACs; labeling packages containing RACs; sorting, grading, or culling RACs; and drying RACs for the purpose of storage or transport.

Table 3 provides examples of how we would classify activities conducted off-farm and on-farm (including farm mixed-type facilities) using these proposed definitions.

TABLE 3—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM

[including farm mixed-type facilities]

Classification	Off farm	On farm (including farm mixed-type facilities)
Harvesting	**Notes:** Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities.	**Notes:** Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting is limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that change a RAC into processed food. Activities that are harvesting are within the farm definition.
	Examples: Not applicable	**Examples:** activities that fit this definition when performed on a farm's ''own RACs'' (a term we use to include RACs grown or raised on that farm or another farm under the same ownership) include gathering, washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling. These activities, performed on a farm's own RACs, are inside the farm definition.
Packing	**Notes:** Placing food in a container other than packaging the food (where packaging means placing food into a container that directly contacts the food and that the consumer receives).	**Notes:** Placing food in a container other than packaging the food (using the same definition of packaging), or activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on that farm or another farm under the same ownership for storage or transport. Packing does not include activities that change RAC into a processed food. Activities that are packing are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
	Examples: putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates).	**Examples:** activities that fit the definition of packing when performed on a farm's own RACs include packaging, mixing, coating with wax/oil/resin for the purpose of storage or transport, stickering/labeling, drying for the purpose of storage or transport, and sorting/grading/culling. These activities, performed on a farm's own RACs, are inside the farm definition. Activities that fit the definition of packing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, include putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates)—the same activities that fit the definition of packing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.
Holding	**Notes:** Storage of food	**Notes:** Storage of food, or activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on that farm or another farm under the same ownership. Holding does not include activities that change a RAC into a processed food. Activities that are holding are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
	Example: storing food, such as in a warehouse	**Examples:** activities that fit the definition of holding when performed on a farm's own RACs include fumigating during storage, and storing food, such as in a warehouse. These activities, performed on a farm's own RACs, are inside the farm definition.

TABLE 3—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM—Continued

[including farm mixed-type facilities]

Classification	Off farm	On farm (including farm mixed-type facilities)
		An activity that fit the definition of holding when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, is storing food, such as in a warehouse—the same activity that fits the definition of holding off farm. This activity, performed on food other than a farm's own RACs, is outside the farm definition unless done on food for consumption on the farm.
Manufacturing/Processing	**Notes:** Making food from 1 or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that consumer receives). **Examples:** activities that fit this definition include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing.	**Notes:** Making food from 1 or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food; except for things that fall into the categories of harvesting, packing, or holding (see rows above). Activities that are manufacturing/processing are outside the farm definition unless done on food for consumption on the farm. **Examples:** activities that fit the definition of manufacturing/processing when performed on a farm's own RACs include slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, coating with things other than wax/oil/resin, drying that creates a distinct commodity, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing. These activities, performed on a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm. Activities that fit the definition of manufacturing/processing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing—the same activities that fit the definition of manufacturing/processing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.

ii. Proposed Definitions of ''Very Small Business'' and ''Small Business''

SUMMARY OF PROPOSED QUALIFICATIONS

[on a rolling basis, average annual monetary value of food sold during the previous three-year period]

Above $250,000 and no more than $500,000	Small Business.
Above $25,000 and no more than $250,000	Very Small Business.
$25,000 or less	Excluded from coverage.

As required by section 419(a)(3)(F) of the FD&C Act, proposed § 112.3(b) defines the terms ''very small business'' and ''small business'' for purposes of this proposed rule only. FDA uses a measure of the average annual monetary value of food sold to determine farm size. This measure should serve as a valid proxy for both the volume and value of production within size category and commodities. The USDA National Commission on Small Farms recommended a definition for a small farm as a family farm with less than $250,000 annual monetary value of all commodities sold (Ref. 85). The Commission's recommendation was based on the reasoning that these farms are the likeliest to exit the industry, and have the greatest need to improve net farm incomes Ref. 85). The Commission states that although 94% of all U.S. farms generate less than $250,000 annual monetary value of all commodities sold, their revenue constitutes only 41% of total gross revenue from all farms (Ref. 85). We propose to use the $250,000 annual monetary value of food sold threshold for our cutoff of a very small farm since the revenue of covered produce farms below this threshold constitutes only 12% of total gross revenue from food

sales by produce farms and make up 83% of all produce farms. We propose to use the statutory cutoff of $500,000 annual monetary value of food sold as one part of the criteria for the qualified exemption in section 419(f) of the FD&C Act (implemented in proposed § 112.5) as the threshold for a small farm. Farms below the $500,000 annual value of food sold cutoff make up 89% of covered farms, and their revenue constitutes 18% of total gross revenue from food sales by produce farms. We developed this proposed definition using sales class breaks found in generally available information from USDA (Ref. 86).

Proposed § 112.3(b)(1) would define your farm to be a very small business if it is subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food you sold during the previous three-year period is no more than $250,000.

Proposed § 112.3(b)(2) would define your farm to be a small business if it is subject to proposed part 112 and, on a rolling basis, the average annual monetary value of food you sold during the previous three-year period is no more than $500,000; and your farm is not a very small business as provided in proposed § 112.3(b)(1).

For clarity, in both proposed § 112.3(b)(1) and (2), the limitation ''if it is subject to this part'' is intended to exclude farms not subject to the proposed rule per proposed § 112.4(a), that is, farms with $25,000 or less of annual value of food sold. As discussed in section V.A.2.c of this document, we propose to exclude such farms from the coverage of this proposed rule such that there would be no reason for them to be classified as small or very small businesses.

iii. Additional Proposed Definitions

Proposed § 112.3(c) would establish the following additional definitions that would apply for the purposes of part 112.

We propose to define ''adequate'' to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. This proposed definition is the same as the definition we have established in § 110.3 with respect to current good manufacturing practice in manufacturing, packing, or holding human food. We have been applying this definition for the purpose of enforcing the regulations in part 110 for more than 40 years and tentatively conclude that it would be an appropriate definition to apply to part 112 as well. Throughout this document, we provide examples of what we mean by ''adequate'' for purposes of complying with specific proposed provisions.

We propose to define ''adequately reduce microorganisms of public health significance'' to mean reduce the presence of such microorganisms to an extent sufficient to prevent illness. This proposed definition would establish in part 112 a definition that we have used in guidance associated with the risk of foodborne illness from pathogens (Ref. 87. Ref. 88). As discussed in those documents, the extent of reduction sufficient to prevent illness is usually determined by the estimated extent to which a pathogen may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1,000 (*i.e.,* 3 logs) Salmonella organisms per gram of food, and a safety factor of 100 (*i.e.,* 2 logs) is employed, a process that adequately reduces Salmonella spp. would be a process capable of reducing *Salmonella* spp. by 5 logs per gram of food.

We propose to define ''agricultural tea'' to mean a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. We developed this term to cover a wide range of ''teas'' used in production of fresh produce, but not to include ''tea'' served as a beverage. The term ''agricultural tea'' was based in part on the definition of ''compost tea'' developed by the National Organic Standards Board (Ref. 89). Human waste would be excluded for consistency with proposed § 112.53 regarding the use of human waste as a soil amendment. The one hour limitation is intended to distinguish between agricultural teas and other liquids such as leachate and runoff and is consistent with the recommendations of the recommendations of the National Organic Standards Board (Ref. 36).

We propose to define ''agricultural tea additive'' to mean a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass. The term ''agricultural tea additive'' was based in part on the definition of ''compost tea additive'' developed by the National Organic Standards Board (Ref. 89).

We propose to define ''agricultural water'' to mean water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). This proposed definition is different from our definition of agricultural water in our Good Agricultural Practices guide (Ref. 10) both because it is not limited to water in the growing environment, and because we have excluded water that does not contact covered produce from this definition based on the information in our QAR.

We propose to define ''animal excreta'' to mean solid or liquid animal waste. By contrast, we are proposing to define ''manure'' to mean animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment. We are proposing definitions to distinguish ''animal excreta'' from ''manure'' based on whether the animal excreta is used as a soil amendment because some proposed requirements make such a distinction. For example, the proposed requirements in §§ 112.54 and 112.56 are directed to the treatment and safe application of biological soil amendments of animal origin, including manure intentionally used as a soil amendment, and the proposed requirements in §§ 112.82 and 112.83 would be directed to preventing contamination of covered produce with animal excreta deposited by wild or domestic animals that intrude in an area where a covered activity is conducted on covered produce. The proposed definition of ''manure'' also accounts for the potential inclusion of animal litter that is collected with animal excreta, *e.g.,* from barns.

We propose to define ''application interval'' to mean the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied. The proposed definition would provide a simple term to use when describing such a time interval. The proposed application intervals for biological soil amendments in proposed § 112.56 would establish requirements regarding such time intervals.

We propose to define ''biological soil amendment'' to mean any soil

amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. We are proposing this definition as a means to distinguish soil amendments that contain biological components from those that do not (like chemical fertilizers). In addition, we propose to define ''biological soil amendment of animal origin'' to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ''biological soil amendment of animal origin'' does not include any form of human waste. We are proposing this definition as a means to distinguish these biological soil amendments from soil amendments that are wholly plant-based (such as yard trimmings).

We propose to define ''composting'' to mean a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions. The proposed definition is consistent with definitions or explanations of ''compost'' and ''composting'' in documents such as a State regulation (Ref. 90), Appendix B to 40 CFR part 503 (Ref. 91), documents prepared by the U.S. EPA (Ref. 92), and the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27).

We propose to define ''covered activity'' to mean growing, harvesting, packing, or holding covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership. Covered activities would not include manufacturing/processing within the definition elsewhere in proposed § 112.3(c). As discussed in sections III.F and V.A.2.b.i of this document, manufacturing/processing on a farm is potentially subject to the coverage of Section 418 of the FD&C Act, unless all of the food used in such activities is consumed on that farm or another farm under the same ownership. Where all of the manufactured/processed food is consumed on that farm or another farm under the same ownership, the activity would be potentially within the scope of Section 419 of the FD&C Act and this proposed rule, except that Section 419(g) of the FD&C Act specifies that ''[t]his section shall not apply to produce that is produced by an individual for personal consumption,'' and section 419(c)(1)(B) of the FD&C Act also requires that FDA ensure that the final rule is practicable for ''a small food processing facility co-located on a farm.''

FDA tentatively concludes that on-farm manufacturing/processing activities for on-farm consumption (like produce for individual consumption) should not be subject to this rule, either because it is automatically excluded by Section 419(g) or because, to the extent there may be any difference between produce ''for personal consumption'' and produce ''consumed on the farm or another farm under the same ownership,'' it is appropriate to exclude on-farm manufacturing/processing for on-farm consumption from the rule. The definition of covered activity would also specify, for clarity, that this part does not apply to activities of a facility that are subject to part 110 of this chapter .

We propose to define ''covered produce'' to mean produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term ''covered produce'' refers to the harvestable or harvested part of the crop. We are proposing to define ''covered produce'' to provide a simple term to use when describing food that would be within the scope of the rule under proposed § 112.1 and not exempt from the rule under proposed § 112.2.

We propose to define ''curing'' to mean the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. This proposed definition is consistent with definitions of ''curing'' in a State regulation (Ref. 93), documents prepared by the U.S. EPA (Ref. 92), and a glossary of composting terms prepared by the Cornell Waste Management Institute (Ref. 94).

We propose to define ''direct water application method'' to mean using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. This proposed definition would provide a simple term to use when describing such water within regulations such as proposed § 112.44(c). By cross-reference to the definitions of ''covered produce'' and ''produce'', this term only applies to methods in which the water is intended to, or is likely to, contact the harvestable part of the covered produce.

We propose to define ''food'' to mean food as defined in section 201(f) of the FD&C Act and to include seeds and beans used to grow sprouts. We have long considered seeds and beans used to grow sprouts to be ''food'' within the meaning of section 201(f) of the FD&C Act (Ref. 95). Seeds and beans used to grow sprouts are both articles used for food and articles used for components of articles used for food. We are proposing to include them specifically in the definition of food for purposes of this rule for clarity because sprouts are covered by this rule.

We propose to define ''food-contact surfaces'' to mean those surfaces that contact human food and those surfaces from which drainage or other transfer onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes food-contact surfaces of equipment and tools used during harvest, packing, and holding. This proposed definition of ''food-contact surfaces'' is consistent with the definition of this term in § 110.3 except that we propose to add the phrase ''or other transfer'' after ''drainage'' definition of ''food-contact surfaces'' to clarify that surfaces from which any transfer involving liquids or non-liquids onto the food or onto surfaces that contact the food are food-contact surfaces.

We propose to define ''hazard'' to mean any biological agent that is reasonably likely to cause illness or injury in the absence of its control. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, Federal HACCP regulations for seafood, juice, and meat and poultry, except that for the purposes of this rule the term would be limited to biological hazards because, as discussed in section IV.A. of this document, this proposed rule is only addressing biological hazards. The NACMCF HACCP guidelines (Ref. 41) and our HACCP regulation for juice (§ 120.3(g)) define ''hazard'' and ''food hazard,'' respectively as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The Codex HACCP Annex defines ''hazard'' as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Ref. 96). Our HACCP regulation for seafood (§ 123.3(f)) and the FSIS HACCP regulation for meat and poultry (9 CFR 417.1) define ''food safety hazard'' as any biological, chemical, or physical property that may cause a food

to be unsafe for human consumption. We recognize that there are other hazards relevant to produce safety on farm that would not be addressed in this proposed rule such as chemical, physical, and radiological hazards (see section IV.B. of this document) and do not intend to suggest by this definition that such hazards are not hazards. We request comment on whether we should instead use the term ''biological hazards'' in this rule.

We propose to define ''humus'' to mean a stabilized (*i.e.,* finished) biological soil amendment produced through a controlled composting process. We are proposing to use ''humus'' as the term to identify the final, mature product of composting for the purpose of this rule. Our proposed definition derives from our proposed definitions for ''composting'' and ''curing'' and the Cornell Waste Management Institute's glossary of composting terms (Ref. 94), which defines humus as a complex aggregate made during the decomposition of plant and animal residues; mainly derivatives of lignin, proteins, and cellulose combined with inorganic soil parts. However, other relevant documents (Ref. 27. Ref. 92. Ref. 97) refer to the production of ''humus-like material'' through composting, and humus can be produced by mechanisms other than the action of microorganisms (Ref. 98). We request comment on whether our proposed definition and use of the term ''humus'' for the final product of composting is appropriate for the purpose of this rule, or whether we should use a term other than ''humus,'' such as ''mature compost.''

We propose to define ''manure'' to mean animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment. As discussed above in the definition of animal excreta, this definition is intended to make a distinction between the terms ''manure'' and ''animal excreta.''

We propose to define ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and to include species having public health significance. As proposed, the term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. The substantive difference between this proposed definition and that in current § 110.3 is the addition of protozoa (*e.g., Giardia lamblia*) and microscopic parasites (*e.g., Cyclospora cayetanensis*). Because such microorganisms are relevant to produce safety, we tentatively conclude that it is reasonable to include them.

We propose to define ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control, and, when applicable, to produce an accurate record of the observation or measurement.

We propose to define ''non-fecal animal byproduct'' to mean solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations. This proposed definition reflects the use of a similar term in sources such as the State of Florida's regulations (Ref. 90). However, we are proposing to include more examples of these byproducts than are included in Florida's regulations to clearly communicate what we mean by the term. We propose to define ''pest'' to mean any objectionable animals or insects including birds, rodents, flies, and larvae. This proposed definition is consistent with the definition of ''pest'' in current § 110.3.

We propose to define ''pre-consumer vegetative waste'' to mean solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). As proposed, pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). As proposed, pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants. This proposed definition is consistent with a State regulation (Ref. 90).

For the purpose of this rule, we propose to define the term ''produce'' to mean any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. For the purposes of this rule, we propose to define ''fruit'' as the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower; and ''vegetable'' as the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

For the purposes of this rule, produce does not include ''food grains'' meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans. With this definition, we are proposing to specifically include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs, and specifically exclude food grains. We explain our proposed definition of ''produce'' in detail above, in section V.A.2.a of this document. We request comments on our proposed definition of ''produce.''

We propose to define ''production batch of sprouts'' to mean all sprouts that are started at the same time in a single growing unit (*e.g.,* a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit). Through this definition, we intend to treat as a production batch product that would be exposed to the same conditions during sprouting, such as multiple seed types grown in a common drum or multiple trays in a single rack that may be exposed to water that has contacted other product in the same growing unit. This term is used in proposed subpart M. Limiting the definition of ''production lot'' to a single growing unit would prevent sprout growers from ''pooling'' samples from multiple growing units within an operation whereby contamination in spent water in one unit could be diluted by non-contaminated water from other units to

the point where pathogens might not be detected. This proposed definition is consistent with our 1999 guidance for industry on sampling and microbial testing of spent irrigation water during sprout production (Ref. 15). We recognize that there are a diversity of growing practices and a variety of growing units that may represent different product volumes, so we request comment on this proposed definition.

We propose to define ''qualified end-user,'' with respect to a food, to mean the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located (i) in the same State as the farm that produced the food; or (ii) not more than 275 miles from such farm. The definition would also state that the term ''consumer'' does not include a business. This definition implements section 419(f)(4) of the FD&C Act. We note that section 419(f)(4)(A) of the FD&C Act does not provide for a different analysis for when an international border falls within the 275 miles; thus, we tentatively conclude that international borders should not affect the distance calculation. Thus, for example, a farm in Mexico selling food to a restaurant or retail food establishment in the U.S. that is within 275 miles of the farm could count that sale as a sale to a qualified end user. As another example, the same would also be true for a U.S. farm selling food to a restaurant or retail food establishment in Mexico that is within 275 miles of the farm. Finally, we also note that the requirements related to distance (in the same state or within 275 miles of the farm) only apply to restaurants and retail food establishment customers, and not to consumers. Thus, a farm may count any sale directly to a consumer as a sale to a qualified end-user.

We propose to define ''raw agricultural commodity (RAC)'' to mean ''raw agricultural commodity'' as defined in section 201(r) of the FD&C Act. We propose to include this reference to the FD&C Act definition to provide additional clarity regarding the meaning of this term.

We propose to define ''reasonably foreseeable hazard'' to mean a potential hazard that may be associated with the farm or the food. We provide a proposed definition for this term as it is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements proposed in this rule. As noted in the discussion of the proposed definition of ''hazard'' in this section, this definition would be limited to biological hazards because those are the only hazards we are currently proposing to address in this rule. We recognize that there are other reasonably foreseeable hazards relevant to produce safety on farm that would not be addressed in this proposed rule such as chemical, physical, and radiological hazards (see section IV.B of this document) and do not intend to suggest by this definition that such hazards are not reasonably foreseeable. We request comment on whether we should instead use the term ''reasonably foreseeable biological hazards'' in this rule.

We propose to define ''sanitize'' to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. This proposed definition is consistent with the existing § 110.3 definition for ''sanitize'' except that we propose to include the term ''cleaned'' before ''food-contact surfaces.'' It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. 99). This proposed definition is consistent with the definition of ''sanitize'' in § 111.3.

We propose to define ''sewage sludge biosolids'' to mean the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of 'sewage sludge' in 40 CFR 503.9(w). This proposed definition is consistent with that of the U.S. Environmental Protection Agency (EPA), which has regulatory jurisdiction over treated domestic sewage and has established terms to describe specific types of treated waste.

We propose to define ''soil amendment'' to mean any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. This proposed definition is consistent with commonly used definitions in industry guidelines and marketing agreements (Ref. 46. Ref. 31). We also propose to include within the meaning of ''soil amendment'' growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts). While this inclusion is not consistent with the common usage of the term, it provides convenience since it is addressing the identical standards that we are proposing for identical hazards that exist for such growth media and soil amendments.

We propose to define ''spent sprout irrigation water'' to mean water that has been used in the growing of sprouts. This definition is intended to minimize the potential for confusion between spent sprout irrigation water and water used for irrigation of other types of covered produce.We are proposing to define ''static composting'' to mean a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. As proposed, examples of structural features for introducing air would include embedded perforated pipes and a constructed permanent base that includes aeration slots. As proposed, examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure). The proposed definition derives from definitions and explanations of ''static composting'' in documents such as prepared by the U.S. EPA (Ref. 92), the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27), and a report from the Food and Agriculture Organization of the United Nations (Ref. 100).

We propose to define ''surface water'' to mean all water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances. This proposed definition is consistent with EPA's definition and with common usage of the term ''surface water'' (Ref. 101). We propose to define this term to distinguish ''surface water'' from other water, such as water from an underground aquifer that has not been held or conveyed in a manner open to the environment (''ground water'') because there is a greater likelihood that surface water could become contaminated, for example, by surface runoff.

We propose to define ''table waste'' to mean any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail

operations, or other sources where the food has been served to a consumer. This definition is intended to distinguish post-consumer food waste from pre-consumer vegetative waste.

We propose to define ''turned composting'' to mean a process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections. The proposed definition is consistent with definitions or explanations of ''windrow composting'' in documents prepared by the U.S. EPA (Ref. 92. Ref. 91), the Produce Safety Project Issue Brief on Composting of Animal Manures (Ref. 27), and a report from the Food and Agriculture Organization of the United Nations (Ref. 100). We are proposing to use the term ''turned composting'' rather than ''windrow composting'' so that the term describing this method would not be limited to use in ''rows.''

We propose to define ''water distribution system'' to mean a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings. The proposed definition would provide a simple term to use when describing such systems.

We propose to define ''we'' to mean the U.S. Food and Drug Administration.

We propose to define ''yard trimmings'' to mean purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils. This proposed definition is consistent with a definition in State composting regulations (Ref. 90), except that we are proposing to use the term ''yard trimmings'' rather than ''yard trash.'' We are proposing to use the term ''yard trimmings'' to avoid potentially negative connotations associated with the word ''trash,'' even though some components of our proposed definition (*e.g.,* untreated wooden pallets) arguably are not ''trimmings.'' We request comment on whether our proposed use of the term ''yard trimmings'' is appropriate for the purpose of this rule, or whether we should propose to use a term other than ''yard trimmings,'' such as ''yard trash'' or ''yard waste.''

We propose to define ''you'' to mean a person who is subject to some or all of the requirements in this part.

c. Persons Subject to This Rule

Proposed § 112.4(a) states that, except as provided in paragraph (b) of that section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as ''food'' is defined in § 112.3(c)) sold during the previous three-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part; however, specific exemptions and partial exemptions apply. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce. We are proposing to apply this proposed rule only to farms and farm mixed-type facilities with an average annual monetary value of food (as ''food'' is defined in § 112.3(c)) sold during the previous three-year period of more than $25,000 (on a rolling basis) because we have tentatively concluded that farms with $25,000 or less in sales do not contribute significantly to the produce market. Farms below the $25,000 limit collectively account for only 1.5% of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. We note that such farms are and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug, and Cosmetic Act and applicable implementing regulations, irrespective of whether they are included within the scope of this proposed rule.

As proposed, § 112.4(a) would make clear that the rule applies to both farms and farm mixed-type facilities, and that such entities would be subject to the rule when they conduct a covered activity on covered produce, as those terms are defined in proposed § 112.3(c). This would mean that, for example, a farm mixed-type facility that is a covered farm and that grows, harvests, packs, and holds its own lettuce would be subject to the proposed rule when conducting those activities (unless an exemption applies, such as that in proposed § 112.4(b)). However, the covered farm would not be subject to the rule when conducting other activities that are not covered activities, or when conducting operations on food other than covered produce. For example, if the farm mixed-type facility applied a manufacturing/processing step (such as chopping) to its lettuce for distribution into commerce (*i.e.,* not for consumption on the farm or another farm under the same ownership, or for personal consumption), this would not be a ''covered activity'' as that term is defined in proposed § 112.3(c) and would therefore not be subject to this rule. In proposed § 112.4(b), we propose to state that you are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part. This implements section 419(f) of the FD&C Act and is discussed further immediately below.

d. Qualified Exemptions

i. Criteria for Eligibility for a Qualified Exemption

Proposed § 112.5(a) establishes the criteria for eligibility for a qualified exemption and associated special requirements based on average monetary value of all food sold and direct farm marketing. This exemption is mandated by Section 419(f) of the FD&C Act. Except as provided in § 112.6, you would be exempt from all of the requirements of this part, except proposed subparts except A, Q, and R, in a calendar year if:

- During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food you sold directly to qualified end-users during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period (§ 112.5(a)(1)); and
- The average annual monetary value of all food you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation (§ 112.5(a)(2)).

Proposed § 112.5(b) provides that, for the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 419(f)(1)(B) of the FD&C Act allow adjustment for inflation. To establish a level playing field for all farms that may satisfy the criteria for the qualified exemption, we are proposing to establish the baseline year for the calculation in proposed § 112.5(a)(2). We are proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law.

Section 419(f) of the FD&C Act does not specifically target arrangements such as community-sponsored agriculture (CSA), you-pick operations,

or farmers markets. It does seem likely that many such operations will meet the criteria for qualified exemption. Each such operation would need to analyze its sales under the terms of § 112.5 to determine its eligibility for the qualified exemption. For example, if a you-pick operation has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000, and all of its sales were to individuals who come to the farm to pick their own produce, all of its sales would be sales to consumers (who are qualified end-users, regardless of location) for the purpose of determining the proportion of the sales that are to qualified end-users. In this example, the you-pick farm would be eligible for the qualified exemption. As another example, if a CSA farm has an average annual monetary value of food sold during the relevant 3-year period of less than $500,000; and 25% of the monetary value of its sales comes from sales to individual consumers enrolled in the CSA, 50% of the monetary value of its sales comes from sales to restaurants in the same state as the farm, and 25% of the monetary value of its sales comes from sales to other buyers who are not qualified end-users; the CSA farm would be eligible for the qualified exemption. In this example, the CSA farm's sales to qualified end-users (consumers and in-state restaurants) make up 75% of the average annual monetary value of food sold, so the value of the farm's sales to qualified end-users exceed the value of its sales to all other buyers during the relevant time period.

ii. Applicable Requirements for Qualified Exemptions

Proposed § 112.6 establishes the requirements that apply to you if you are eligible for a qualified exemption in accordance with § 112.5. Proposed § 112.6(a) explains that subparts A, Q, and R remain applicable to those who qualify for a qualified exemption under § 112.5. This is because subpart A contains this provision and other general provisions such as definitions, Subpart Q contains provisions related to compliance and enforcement, and subpart R contains provisions necessary to implement section 419(f)(3) of the FD&C Act, as discussed further in section V.R. of this document. Consistent with section 419(f)(2) of the FD&C Act, proposed § 112.6(b) establishes the modified requirements (label or point of purchase display) applicable to those who meet the requirements under § 112.5 for a qualified exemption.

Specifically, proposed § 112.6(b)(1) would require that, when a food packaging label is required on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, you include prominently and conspicuously on the food packaging label the name and complete business address of the farm where the produce was grown. Proposed § 112.6(b)(2) requires that, when a food packaging label is not required on food that would otherwise be covered produce under the FD&C Act, you prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown. As proposed, the name and address of the farm must be displayed on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice. That is, if a label is otherwise required on the produce that would otherwise be covered (for example, tomatoes in a ''clam shell'' package) then the label must include the name and business address of the farm where the produce was grown. If a label is not required (for example, unpackaged tomatoes) then the name and business address of the farm where the produce was grown must be displayed at the point of purchase (such as on a poster, for example). These proposed provisions reflect our interpretation of section 419(f)(2)(A)(i) and (ii) as applying only to food that would otherwise be covered produce but for the qualified exemption. We tentatively conclude that this interpretation is reasonable because applying these consumer notification requirements to food that would not otherwise be covered produce would mean applying requirements to food that bears no relationship to the subject of this rulemaking (*e.g.,* to milk from a farm that also grows and harvests produce and that meets the criteria for the qualified exemption from this proposed rule).

Proposed 112.6(b)(3) states that the complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms. Proposed § 112.6(b)(3) would enable consumers to contact the farm where the food that would otherwise be covered produce was grown (*e.g.,* if the consumer identifies or suspects a food safety problem with a the produce) irrespective of whether the produce bears a label. The use of the term ''business address'' in section 419(f)(2)(A) of the FD&C Act contrasts with Congress' use of a different term, ''place of business,'' in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. Our regulations interpret ''place of business'' as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 CFR 101.5(d)). We tentatively conclude that the use of the term ''business address'' in section 419(f)(2)(A) demonstrates Congress' intent to require the farm's full address, including the street address or P.O. box, to appear on labels or other required notifications when the farm qualifies for the exemption in section 419(f) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the ''place of business'' labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 419(f)(2)(A)(1) for the farm's ''business address'' to appear on the food label. Requiring the complete business address for this purpose is consistent with our guidance to industry on the labeling of dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Ref. 103). When proposed § 112.5(b) would apply to a food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the ''place of business'' required under section 403(e)(1) of the FD&C Act and 21 CFR 101.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. We seek comment on the feasibility of the labeling provisions in proposed 112.6(b), particularly in the case of consolidating produce from several farm locations.

Section 419 of the FD&C Act does not explicitly require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption. FDA considers that it may be necessary for farms to maintain such records, and to allow FDA access to such records upon

request, in order to efficiently enforce section 419 of the FD&C Act. Otherwise we would have no way to determine whether a farm claiming the qualified exemption actually met the criteria for that exemption. This could be important, for example, if a farm claiming the qualified exemption is directly linked to a foodborne illness outbreak during an active investigation or if FDA determines, based on conduct or conditions associated with the farm that are material to the safety of the food produced or harvested at such farm, that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak to withdraw the farm's qualified exemption (see section V.R. of this document discussing proposed subpart R). Because the withdrawal procedure in proposed subpart R would only apply to farms that are eligible for the qualified exemption, we would need to know whether the farm is indeed eligible for the exemption in order to select the appropriate and efficient enforcement strategy. We request comment on whether we should require farms to be able to provide adequate documentation, as needed, to demonstrate the basis for the qualified exemption. Specifically, we request comment on whether we should do this by requiring records to be established and maintained in accordance with the requirements of proposed subpart O, or if there is an alternative strategy by which we could require retention of and access to such records (such as by requiring farms only to retain records kept in the normal course of their business bearing on the criteria for the qualified exemption that they use to determine their eligibility and requiring FDA access to such records upon request).

B. Subpart B—General Requirements

As proposed, subpart B discusses the general requirements applicable to persons who are subject to this part and alternatives from the requirements established in this part that would be permitted, under specified conditions.

1. Comments Relevant to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to the general requirements established in this subpart of the rule. A consumer organization urged FDA to take additional steps to ensure the safety of bagged salads and all leafy greens. Some comments recommended that FDA include in this rule an amendment mechanism that can expeditiously accommodate new scientific knowledge.

Section 402 of the FD&C Act specifies conditions under which a food is deemed adulterated, including if the food bears or contains any added poisonous or deleterious substance which may render it injurious to health (402(a)(1)); if it is unfit for food (402(a)(3)); or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (402(a)(4)). In proposed § 112.11, we would specifically require that covered farms take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce as well as to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. Such hazards would include all pathogens to the extent that they pose a risk of serious adverse health consequences or death, including *Salmonella* and *E. coli* O157:H7, in all covered produce raw agricultural commodities, including leafy greens. With respect to bagged salads, we note that such salads are manufactured in facilities that are required to register with us and, therefore, would be covered under section 418 of the FD&C Act and any regulations promulgated pursuant to that authority, rather than by this proposed rulemaking.

We recognize the value in making this regulation flexible, where appropriate, to accommodate future changes in science and technology. In proposed § 112.12, we list the specific requirements established in this rule for which we believe alternatives may be appropriate and the circumstances under which such alternatives could be used. In addition, consistent with section 419(c)(2) of the FD&C Act, in proposed subpart P, we provide for a mechanism by which a State or a foreign country from which food is imported into the United States may request a variance from one or more requirements proposed in this part, where the State or foreign country determines that: (a) The variance is necessary in light of local growing conditions; and (b) the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part (see section V.P. of this document). We also intend to publish guidance, as appropriate, to provide updates on current thinking with respect to best practices in produce safety.

2. Proposed Requirements

a. General Requirements Applicable to Persons Subject to This Part

As proposed, § 112.11 establishes the general requirements applicable to persons who are subject to this rule. Proposed § 112.11 requires that you take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards.

This provision is consistent with the requirements of section 419(c)(1)(a) of the FD&C Act, which mandates, in relevant part, that we publish regulations that ''set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, * * * into fruits and vegetables, * * * and to provide reasonable assurances that the produce is not adulterated under section 402.'' As discussed in section IV.B. of this document, we have tentatively concluded that this rule should focus solely on biological hazards.

In subparts C to O, we propose science-based minimum standards related to the growing, harvesting, packing, and holding of covered produce that we believe are necessary to minimize the risk of serious adverse health consequences or death by preventing the introduction of hazards and providing reasonable assurances that the covered produce is not adulterated.

Proposed § 112.11 would require, for example, that whenever a standard specified in this part is not met, you would take those steps reasonably necessary to identify and evaluate the cause of the problem and ensure that it is rectified. Accurate identification of

the cause of the failure is critical to the success of any potential corrective actions. For example, if your employees are having difficulty identifying covered produce that should not be harvested due to potential contamination, you might initially think the answer is to provide more frequent training; however upon investigation, you may discover that the actual cause of the problem is that your employee training program is providing inaccurate information. In this case, to correct the problem, you would need to fix your training program. Promptly taking such follow-up actions once the cause of the problem has been identified is necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, your covered produce and to provide reasonable assurances that the product is not adulterated under section 402 of the FD&C Act.

In addition, proposed § 112.11 would require you to take appropriate measures to minimize risks of serious adverse health consequences or death from the use of, or exposure to, covered produce that may arise unexpectedly and therefore not be reflected in a specific standard set forth in proposed subparts C to O of this rule. For example, in the event of an unexpected event, such as receipt of information suggesting that your covered produce from a particular field is adulterated because it bears or contains a pathogen that may render the produce injurious to health, proposed § 112.11 would require you to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, your covered produce by preventing the introduction of biological hazards into or onto your produce or by taking measures to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. Such measures might include, for example, conducting a root cause investigation to try to determine the source of the contamination, making appropriate changes to your conditions and practices suggested by the root cause investigation, including to produce in other fields, as appropriate, determining the extent of the impact of the root cause (*i.e.,* within the suspect field and in other fields), and excluding adulterated produce from commerce. We note, however, that we do not intend for proposed § 112.11 to suggest that you would need to take measures to exclude animals from outdoor growing areas, to destroy animal habitats near your outdoor growing areas, to clear farm borders around outdoor growing areas or drainages, or to take any action that would violate applicable environmental laws or regulations.

We propose to include proposed § 112.11 in order to account for the variety of possible circumstances that might arise in which an unexpected circumstance or unique farm characteristics would justify preventive measures to prevent introduction of hazards or provide assurances against adulteration in order to minimize the risk of serious adverse health consequences or death. We request comment on this approach, and on whether we should instead establish specific standards for any types of hazards that would be covered in proposed § 112.11 but for which we have not proposed specific standards in proposed subparts C through O.

b. Alternatives to Certain Requirements

As proposed, § 112.12 allows for the use of alternatives to certain requirements of this part. Subparagraph (a) lists the specific requirements for which alternatives may be considered provided you are in compliance with subparagraphs (b) and (c), which describe the conditions for use of an alternative. Proposed § 112.12(b) states that you may establish and use an alternative to any of the requirements listed in paragraph (a), provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part (including meeting the same microbiological standards, where applicable) and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval. We do not propose to require you to submit such scientific data or information to us for review or approval prior to marketing. However, we would require that you maintain a record of any such scientific data or information, including any analytical information, and make such data and information available to us to evaluate upon request.

Proposed § 112.12(c) clarifies that the scientific data and information used to support an alternative to a requirement may be developed by you, available in the scientific literature, or available to you through a third party, and further provides that documentation of such data and information must be established and maintained in accordance with the requirements of subpart O of this part. As discussed in section II.E.4. of this document, FDA is collaborating with partners on research that may provide scientific support for specific alternatives to certain of these requirements. FDA intends to issue guidance on specific alternatives that it may identify as meeting the requirements of the rule in order to assist farms in complying with the final rule. For example, a farm that applies crop protection sprays to the harvestable portion of crops (*i.e.,* application of water containing crop protection substances using a direct water application method) several days before the crop is harvested using a water source that does not meet the requirements of § 112.44(c) (i.e, EPA generic *E. coli* ''recreational water'' standard), may use an alternative measure provided by their Cooperative Extension agent, for example, as long as the measure is based on scientifically sound data and meets the conditions described above (*i.e.,* provides the same level of public health protection as the applicable requirement and does not increase the likelihood that covered produce will be adulterated). For example, the study might demonstrate that the quality of water used for direct application method irrigation is not important as long as there are at least two days between application and harvest, or that water of some lesser standard than that in § 112.44(c) could safely be applied immediately before harvest. The farm operator would maintain a copy of the information provided by the agent as documentation that the alternative measure was based on sound science. When FDA becomes aware of such information, it is our intention to include it in guidance, so that farm operators can also rely on FDA guidance for such alternative measures.

As proposed in § 112.12(a), you may establish alternatives to the following requirements:

(1) The requirements in § 112.44(c), for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method;

(2) The composting treatment processes required in § 112.54(c)(1) and (2);

(3) The minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin; and

(4) The minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process.

Under proposed § 112.12(a)(1), you may establish an alternative to the requirements, established in proposed § 112.44(c) for testing water, and taking action based on test results when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method. Under proposed § 112.44(c), you must test the quality of water you use during growing activities for covered produce (other than sprouts) in accordance with one of the appropriate analytical methods in proposed subpart N. If you find that there is more than 235 CFU (or MPN, as appropriate) generic E. coli per 100 ml for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in that paragraph and before you may use the water source and/or its distribution system again for those uses, you must either: (1) Re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective, or (2) treat the water in accordance with the requirements of § 112.43. As discussed in section V.E. of this document, we considered several factors and ultimately determined that the microbial standard in proposed § 112.44(c), which is based on certain aspects of U.S. EPA's recreational water standards is appropriate for the uses of agricultural water covered by proposed § 112.44(c). We seek comment on this approach.

However, we acknowledge that in specific circumstances an alternative standard (*e.g.,* a standard that applies an application interval (time between application and harvest) in place of the 112.44(c) water standard, but is limited to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. For example, we are working with USDA and other stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier). Therefore, we tentatively conclude that it would be appropriate to allow for alternatives to the requirements in proposed § 112.44(c).

Under proposed § 112.12(a)(2), you may establish an alternative to the treatment processes, established in proposed § 112.54(c)(1) and (2), for composting, provided you comply with § 112.54(c)(3). The processes established in § 112.54(c)(1) and (2) as scientifically valid controlled composting processes demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and for fecal coliforms are: (1) Static composting that maintains aerobic (*i.e.,* oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation; and (2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation. We tentatively conclude that it would be appropriate to allow for the use of other static or turned composting protocols that maintain conditions for a combination of temperatures and time other than the temperature and times specified in proposed §§ 112.54(c)(1) and (2), and is followed by adequate curing, which includes proper insulation, if they achieve the same level of pathogen reduction (*i.e.,* meet the microbial standard in § 112.55(b)). In this sense, the microbial standards would provide a performance standard; practices that meet this objective measure would be acceptable. It would be your responsibility to consider the moisture content, pH, carbon to nitrogen ratio (C:N), feedstock, and any other appropriate consideration needed during composting to adequately achieve the microbial standards of proposed § 112.55(b).

Under proposed § 112.12(a)(3), you may establish an alternative to the minimum application interval of nine (9) months, established in proposed § 112.56(a)(1)(i), for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives. As discussed in section V.F of this document, we have tentatively concluded that, under certain circumstances, the application interval in § 112.56(a)(1)(i) may be more than what is necessary for minimizing the likelihood that covered produce that is grown in soils amended with an untreated biological soil amendment, and is reasonably likely to contact the soil after application, pose to the public health. These circumstances could include differences in likelihood of contamination posed by the specific feedstock, application method or treatment method, especially given the potential for new innovations in such methods.

Under proposed § 112.12(a)(4), you may establish an alternative to the minimum application interval of 45 days, established in proposed § 112.56(a)(4)(i), for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of proposed § 112.54(c) that satisfies the microbial standard in proposed § 112.55(b), and that is reasonably likely to contact covered produce after application. As discussed in section V.F. of this document, we are proposing a multiple-hurdle approach to minimizing the likelihood of contamination by addition of an application interval of 45 days to any biological soil amendment of animal origin treated by composting that is reasonably likely to contact covered produce after application. This time period has been shown to be effective when the population of the pathogen is minimal (Ref. 104) as can be expected of a fully composted biological soil amendment of animal origin. This multiple hurdle approach and time interval has also been utilized in current industry standards for leafy greens (Ref. 31). We seek comments on this proposal. We have also tentatively concluded that, under certain circumstances, the application interval in § 112.56(a)(4)(i) may be more than what is necessary for minimizing the likelihood of contamination of covered produce that is grown in soils amended with a treated biological soil amendment, and that is reasonably likely to contact the soil after application. These circumstances could include differences in likelihood of contamination posed by the specific feedstock, application method or treatment method, especially given the potential for new innovations in such methods.

As noted above, in any use of alternatives permitted in § 112.12(a)(1) through § 112.12(a)(4), in accordance with proposed § 112.12(b), you would be required to have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the requirement specified

in the proposed rule and would not increase the likelihood that your covered produce will be adulterated under section 402 of the FD&C Act. Further, in accordance with proposed § 112.12(c), you must establish and maintain documentation of such scientific data or information, which may be developed by you, available in the scientific literature, or available to you through a third party. We are working with USDA and other stakeholders to conduct research on relevant alternative practices and intend to make the results of that research available in the future. We seek comment on whether we should require you to notify FDA of your conclusion to establish or use an alternative that is permitted under §§ 112.12(a)(1) through (a)(4), and whether we should require you to submit relevant scientific data or information to FDA as part of such a notification.

C. Subpart C—Standards Directed to Personnel Qualifications and Training

As proposed, subpart C discusses minimum standards directed to personnel qualifications and training that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to personnel qualifications and training. Several comments expressed concern over language and educational barriers greatly impeding the farm's ability to effectively fulfill the training requirements for their field workers. They also stressed the need for far reaching, accurate, consistent, and well-rounded training programs with skilled trainers providing the same information to growers, processors and distributors. Comments further suggested that training materials should have addendums to reflect the differences among the varied growing regions, commodities, and production practices and processes, as well as train-the-trainer programs for individuals responsible for training farm workers. Many firms also urged organizations, universities, and extension agencies to share experiences and to provide resources for worker training. Several comments pointed out difficulties in training due to the transient or short term nature of farm workers and due to the seasonal relocation of their operations. In addition, comments expressed concern over the cost of implementation, including regular refresher courses and training materials, and the reliability of third-party training materials. One comment requested that individuals responsible for the training program and materials should ensure that curricula are updated to reflect any new scientific information.

We believe that adequate and appropriate training of personnel who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, is an essential component of standards for produce safety. Regardless of the nature of the farm workers, we propose that they must receive training upon hiring, at the beginning of each growing season, and with periodic updates as necessary in order to prevent contamination of covered produce. Farm workers need to know how to recognize potential contamination problems (*e.g.,* a leafy green vegetable contaminated with manure) and to be trained to know what to do when those situations present themselves. The farm worker is a key component in the food chain for ensuring the safety of covered produce. No matter the transient nature, any worker can be a potential pathway for contamination of produce during growing, harvesting, packing, and holding (*e.g.,* because of hygiene issues or illness) or fail to identify a situation that may result in contamination of the covered produce being grown, harvested, packed, or held if they are not cognizant of proper food safety procedures and standards. It is not uncommon for workers to change based on season and location and, therefore, proposed § 112.21(a) would require personnel to receive training upon hiring and at the beginning of each growing season (if applicable). Proposed § 112.21(a) would also require that personnel receive periodic updates as a way of reminding them of the proper procedures including any changes in those procedures. Such updates may not require full training sessions, but only short descriptive sessions to ensure that all personnel remain aware of all procedures necessary to maintain the safety of produce.

Together with the USDA, Cornell University's National GAPs program, the Association of Food and Drug Officials (AFDO), and the National Association of State Departments of Agriculture (NASDA), we have formed the Produce Safety Alliance (PSA), which is a public-private partnership established to provide educational outreach assistance to fresh produce growers and packers. This program is in the process of creating training materials that will be both region- and commodity-specific. We expect these materials to be standardized, multi-formatted, and multi-lingual, and available in pictorial format to help overcome literacy issues. Specific focus areas for the PSA include GAPs and co-management education and outreach efforts for produce farmers and packers, with special emphasis on small-scale operations. This alliance will also include a train-the-trainer lesson plan and an education outreach program delivery for farmers, trainers, and regulators. We intend to explore the need for additional such partnerships, as appropriate, to address any commodity-specific needs for outreach and assistance. We welcome comments and suggestions for training development strategies.

2. Proposed Requirements

Proposed § 112.21 would establish requirements for the qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces, or who are engaged in the supervision thereof. Having personnel follow proper food hygiene practices, including personal health and hygiene, can reduce the potential for on-farm contamination of covered produce. Educating personnel who conduct covered activities in which they contact covered produce and supervisors about food hygiene, food safety, and the risks to produce safety associated with illnesses and inadequate personal hygiene is a simple step that can be taken to reduce the likelihood of pathogens being spread from or by personnel to covered produce.

Most current FDA, private and international guidelines for the produce industry include provisions related to training food handlers in the importance of personal health and hygiene to food safety (Ref. 10. Ref. 20. Ref. 50. Ref. 48. Ref. 96. Ref. 26). As described in the QAR, FDA's follow-up farm investigations in response to outbreaks and contamination events identified poor worker health and hygiene, unsafe produce handling and storage practices, and specifically poor training in these areas, as likely contributing factors to these events. This information reinforces the importance of training farm personnel, including supervisors, in food hygiene, food safety, employee health and personal hygiene.

Proposed § 112.21(a) would require that all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors receive training that is appropriate to the person's duties, upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter. Because ensuring that covered produce is not contaminated is dependent on personnel following proper food safety and hygiene practices, all personnel who contact covered produce and food-contact surfaces must receive training when hired, before they participate in the growing, harvest, packing or holding of covered produce in which they contact covered produce, and must be periodically reminded about the need to follow these practices through refresher training. When a farm hires workers after the beginning of a growing season, these workers would need to be trained upon hiring. Because the farm does not employ these workers at the beginning of the first growing season, the requirement for training at the beginning of each growing season would not be applicable to those workers until the beginning of the next growing season, if they are still employed by the farm at that time. Managers and supervisors must have the necessary knowledge of food safety and hygiene principles and practices to be able to assess whether their staff are following appropriate practices, and take the necessary action to remedy any deficiencies, which could include on-the-spot training for their staff.

Periodic refresher training for all relevant personnel, including managers and supervisors, is necessary to ensure continual awareness of important food safety and hygiene principles. It is also important when new information is available about practices that may contribute to foodborne illness or when, for that reason or other reasons, changes in the farm's procedures are put in place. For example, during the past decade several segments of the produce industry reviewed and revised their industry guidelines or developed new guidelines to address current food safety concerns relative their specific commodity (*i.e.,* lettuce, tomatoes, sprouts, and cilantro).

Proposed § 112.21(b) would require that all personnel (including temporary, part time, seasonal and contracted personnel) who handle (contact) covered produce or food-contact surfaces and their supervisors have the training, in combination with education or experience, to perform the person's assigned duties in a manner that ensures compliance with this part. Proposed § 112.21(b) would provide flexibility for how personnel become qualified to perform their assigned duties by recognizing multiple pathways to obtain the necessary qualifications: Training (such as training provided on-the-job), in combination with education, or experience (*e.g.,* work experience related to an employee's current assigned duties). The standards in subparts C through O often involve action by farm personnel (*e.g.,* monitoring of animal intrusion, inspecting agricultural water system) that require specific knowledge, skills and abilities, without which the standard could not be properly achieved. Proposed § 112.21(b) requires that those farm personnel have the training so that they will have the necessary knowledge, skills, and abilities to perform their duties.

Proposed § 112.21(c) would establish requirements for training to be conducted in a manner that is easily understood by personnel being trained. The goals of training cannot be achieved if the person receiving the training cannot understand it. Training could be understood by personnel being trained if, for example, it was conducted in the language that employees customarily speak and at the appropriate level of education. In some cases in may be necessary to use easily understood pictorials or graphics of important concepts (Ref. 105).

Proposed § 112.21(d) would establish requirements for training to be repeated as necessary and appropriate in light of observations or information indicating that personnel are not adequately meeting standards established by FDA in subparts C through O of the rule. The goals of training are not achieved if the persons receiving the training do not correctly implement those standards taught. Moreover, repeated training as proposed in § 112.21(d) is necessary when an employee that does not follow the correct food safety protocol, because such behavior may increase the likelihood of introducing a food safety hazard to covered produce. When an employee requires additional training, it may consist of informal on-the-spot instruction to focus on those measures not being adequately implemented as opposed to more comprehensive training. For example, if you observe an employee commit a minor error, such as an inappropriate method for recording monitoring information in a log, an appropriate action could be to show the employee the correct method of recording the information and contrast this with the inappropriate method the employee had been using. However, if an employee displays repeated mistakes or a fundamental misunderstanding of the correct procedures for handling covered produce, an appropriate action may be to have the employee repeat relevant training, or to attend a comprehensive training course. If you conclude that the employee may not have the skills to conduct certain covered activities, an appropriate action may be to train the employee for new responsibilities that are more suitable to his or her skills.

Proposed § 112.22(a) would require that, at a minimum, all personnel who handle (contact) covered produce during covered activities must receive training that would include: (1) Principles of food hygiene and food safety (proposed § 112.22(a)(1)); (2) the importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance (proposed § 112.22(a)(2)); and (3) the standards as applicable to the employee's job responsibilities, including those established by FDA in subparts C through O of this part (proposed § 112.22(a)(3)).

We tentatively conclude that the broad topic areas addressed in proposed § 112.22(a) are those minimum topic areas necessary to be covered during training for all employees who handle (contact) covered produce. Training in the principles of food hygiene and food safety are necessary to provide an overall framework for job performance. Training in health, hygiene, and disease control can teach workers how to minimize the likelihood of transferring pathogens to covered produce. These topics are covered in several currently used guidance documents (Ref. 10. Ref. 20. Ref. 50. Ref. 48. Ref. 96). In addition, training in the specific standards established in subparts C through O of this part which are necessary for the employee to use during the course of their duties will increase the likelihood that those standards will be implemented correctly and effectively. We seek comments on the scope, frequency, and methods outlined in the proposed training sections of the proposed rule.

Proposed § 112.22(b) would require that persons who conduct covered harvest activities for covered produce also receive training that includes all of the following: (1) Recognizing covered produce that should not be harvested, including covered produce that may be contaminated with known or reasonably

foreseeable food safety hazards (proposed § 112.22(b)(1)); (2) inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable food safety hazards (proposed § 112.22(b)(2)); and (3) correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities (proposed § 112.23(b)(3)).

We tentatively conclude that the topic areas addressed in proposed § 112.22(b), in addition to § 112.22(a), are those minimum topic areas necessary to be covered during training for persons who conduct harvest activities. Harvest workers need to learn how to recognize produce that should not be harvested (such as rotten or decayed fruit, ''drops,'' or harvestable items that have been contaminated with feces), because not harvesting such covered produce would be the first opportunity to prevent that produce from entering commerce, and as a practical matter may be the only such opportunity (for example, during a field-pack operation with no subsequent culling stage). Proposed § 112.112 would require that farms take all measures reasonably necessary to identify and not harvest covered produce that is visibly contaminated with animal excreta.

Harvest workers must be trained to both recognize this condition and to avoid harvesting covered produce that exhibits the condition. Harvest workers also need to know how to inspect harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so that they will not act as a source of contamination or lead to damage of covered produce (damaged produce is more likely to harbor pathogens, and at a greater population, than is sound produce (Ref. 59. Ref. 106)). Harvest workers also need to know how to correct problems with harvest equipment or containers when they encounter them, or need to know that they should report such problems to someone who would be responsible for ensuring that the problem is corrected. These topics are covered in several currently used relevant documents (Ref. 8. Ref. 33. Ref. 18. Ref. 89. Ref. 84). We acknowledge the challenge these training requirements may pose to farms that employ contracted harvest crews. In such cases, we expect that the harvest crew company could provide the required training to workers, who move from farm to farm under the employment of the harvest crew company. Farms on which such harvest crews work could request certification from the harvest crew company that their workers have received the required training. We seek comment on the feasibility of the proposed training requirements, particularly with respect to harvest activities.

Proposed § 112.22(c) would require that at least one supervisor or responsible party for your farm successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. Experience at farming does not necessarily convey knowledge of food safety, particularly that of microbial food safety hazards, and therefore specialized training is needed to address the specific concerns of on-farm food safety. The purpose of training a supervisor or other responsible party is so that person can help train other employees, recognize conditions that could lead to contamination of covered produce, and take action to correct those conditions. As discussed in section II.D. of this document, FDA has, together with USDA AMS, established the jointly funded PSA, a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce growers and packers with fundamental, on-farm food safety knowledge, starting in advance of this proposed rule and continuing after the final regulation is promulgated. A first phase of PSA's work is intended to assist growers, especially small growers, in establishing food safety programs consistent with the GAPs Guide and other existing guidances and requirements so that they will be better positioned to comply with a final produce rule. As this rulemaking progresses, FDA will work to ensure that the PSA materials are modified, as needed, to be consistent with the requirements of this rule. Included in that material will be the standardized curriculum against which FDA intends to compare other training programs. After reviewing the final draft of the PSA training materials, FDA intends to publish a notice of availability of the documents in the **Federal Register**. We would encourage trainers outside the PSA to evaluate their courses, past, present, and future, against the PSA materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance course. We have no plans to publish a list of ''approved'' courses other than the Alliance course materials. Proposed § 112.23 would require that you assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of the rule. Oversight by a qualified individual is essential to the effective implementation of the rule. Under proposed § 112.23, the personnel that you assign or identify to supervise (or otherwise be responsible for) your operations may be a single person (including yourself), or may be a team of individuals, each with specific areas of responsibility (*e.g.,* you may assign or identify separate persons to be responsible for your water distribution system, your harvest activities, your sanitary accommodations, and your packing activities).

Proposed § 112.30(a) would require that you establish and keep records required under subpart C in accordance with the requirements of subpart O of the rule. Proposed § 112.30(b) would require that you establish and keep records that document required training of personnel, including the date of the training, the topics covered, and the person(s) trained. An example of records that would comply with proposed § 112.30(b) is an attendance sheet with the date, list of those in attendance, and the particular topics covered (such as proper hand washing or how to collect samples for water testing). The records required by proposed § 112.30(b) would enable you to track the training personnel receive, thereby enabling you to identify personnel and training topics for periodic updates and personnel that have the prerequisite training for assignment to certain responsibilities. Such records would enable you to document that a person has, as would be required under proposed §§ 112.21(a) and (b), successfully completed training as appropriate to the person's duties, upon hiring and periodically thereafter, including the principles of food hygiene and food safety and also the training that would be specific to a person's tasks and responsibilities.

D. Subpart D—Standards Directed to Health and Hygiene

As proposed, subpart D discusses science-based minimum standards directed to health and hygiene that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or

reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed issues relevant to health and hygiene. Several comments noted the challenges of enforcing use of gloves and clean clothes. Others expressed concerns related to identifying sick employees who could contaminate covered produce or food-contact surfaces, while another comment asked about potential requirements on hygienic practices and questioned whether hand jewelry could contaminate produce such as leafy greens.

We recognize the importance of taking appropriate measures to prevent sick or infected persons from contaminating covered produce or food-contact surfaces. In proposed § 112.22(a)(2), we propose to require training of personnel to recognize symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance. The proposed requirements for standards directed to health and hygiene focus on maintaining adequate personal cleanliness. Gloves can provide a barrier to reduce the potential for contamination; however, gloves themselves can transfer pathogens to covered produce if they become contaminated. Therefore, while we are not proposing to require the use of gloves, we are proposing to require the proper use of gloves when workers wear them (proposed § 112.32(b)(4)). Clothes should be adequately clean if by virtue of type of operation the workers are performing, the clothes could potentially contaminate covered produce with pathogens.

2. Proposed Requirements

Proposed subpart D would require that you take those measures that we tentatively conclude are reasonably necessary to prevent personnel and visitors from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. As discussed above (see sections I.A. of this document, and QAR), people can carry a wide variety of pathogens (including hepatitis A virus, *Salmonella, E. coli* O157:H7, *Shigella, Cyclospora,* and *Cryptosporidium* (Ref. 93) (Ref. 107). Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route (Ref. 95. Ref. 96. Ref. 97. Ref. 98. Ref. 93). Several of the provisions of proposed subpart D are similar to requirements in our Current Good Manufacturing Practice regulations for food and for dietary supplements (§ 110.10 and 111.10, respectively), and to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 46. Ref. 44), a marketing agreement (Ref. 31), and international guidelines (Ref. 96).

Proposed § 112.31 would require that you take measures necessary to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance. Proposed § 112.31(a) would require that you take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

Proposed § 112.31(b)(1) would require that you exclude any person from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation (for example, by a supervisor or responsible party)) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health. Applicable health conditions would not include non-communicable diseases such as cancer, diabetes, or high blood pressure, or non-communicable conditions such as pregnancy, which would not present a likelihood of contamination to covered produce or food contact surfaces. For example, if an employee tells you that his or her physician has diagnosed that the employee has a fever, and the employee normally handles your covered produce, you must take steps to ensure that the employee does not come into contact with your covered produce because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. Likewise, if you see that an employee has an open wound or sore, and the employee normally handles covered produce, you must take steps to ensure that he or she is excluded from handling covered produce if the wound could be a source of microbial contamination. Proposed § 112.31(b)(1) is similar to requirements in current §§ 110.10(a) and 111.10(a) and to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code, various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), and a marketing agreement (Ref. 31), and the Codex Code (Ref. 96).

Proposed § 112.31(b)(2) would require that you instruct your personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition. Consistent with the training requirement proposed in § 112.22(a)(2), we are proposing this requirement as a measure specifically directed at preventing sick or infected persons from contaminating covered produce or food-contact surfaces and to emphasize that individual workers have a responsibility—every day—to take action to prevent contamination due to their own illness or infection. In a small or very small business, such as a farm largely operated by a husband and wife, the impact of proposed § 112.31(b)(2) would, in essence, be for a sick worker to take appropriate steps to exclude himself or herself from working in any operations that may result in contamination of covered produce or food-contact surfaces with pathogens. Proposed § 112.31(b)(2) is similar to requirements in current §§ 110.10(a) and 111.10(a) and to provisions in the AFDO Model Code (Ref. 20), and a produce industry guideline ((Ref. 46). We seek comments on the notification and other proposed requirements related to workers health.

Proposed § 112.32 would require that personnel use certain hygienic practices. Proposed § 112.32(a) would require that personnel who work in an operation in which covered produce or food-contact surfaces are at likelihood of contamination with known or reasonably foreseeable hazards use hygienic practices while on duty to the extent necessary to protect against such contamination. Hygienic practices can prevent introduction of microbial (such as bacteria and viruses that could be present in saliva or on skin) contamination of covered produce (Ref. 108). Inadequate hygienic practices among workers have been associated with outbreaks transmitted by various produce commodities, including strawberries, green onions, mamey, leaf lettuce, and basil (Ref. 107). Proposed § 112.32(a) is similar to requirements in current §§ 110.10(b) and 111.10(b) and to provisions in our GAPs Guide (Ref.

44), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 46. Ref. 44), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96).

Proposed § 112.32(b) would require that personnel who handle (contact) covered produce use specific hygienic practices to satisfy the requirements of proposed § 112.32(a). Proposed § 112.32(b)(1) would require the specific practice of maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces. Requiring that workers maintain adequate personal cleanliness is similar to requirements in current §§ 110.10(b) and 111.10(b) and to provisions in the Codex Code (Ref. 96). We would expect that maintaining adequate personal cleanliness would include wearing adequate outer garments as necessary and appropriate to protect against contamination of covered produce and food-contact surfaces. Outer garments (*e.g.,* smocks, aprons, or coveralls worn over a worker's personal clothing) may be necessary and appropriate when a worker conducts an activity that has increased potential to contaminate the worker's personal garments with hazards that could be transferred to covered produce or food-contact surfaces during subsequent activities in which the worker may contact covered produce. For example, a worker's personal clothing could become contaminated with pathogens while a worker shovels manure, and such contamination could be transferred from the clothing to covered produce if the worker subsequently harvests covered produce wearing the same clothes. An apron, smock, or coverall worn over the worker's personal clothing while shoveling the manure could simply be removed before the worker moves on to a harvest activity, which would reduce the likelihood of contaminating covered produce during the subsequent harvest activity. We intend to provide further information about adequate worker personal cleanliness in guidance.

Proposed § 112.32(b)(2) would require that personnel avoid contact with animals other than working animals, and that personnel in direct contact with working animals take appropriate steps to minimize the likelihood of contamination of covered produce. Pathogens can be directly transmitted from animals to people when persons touch, pet, feed, or are licked by animals because animal hair, fur, saliva and skin can harbor pathogens (Ref. 98. Ref. 99. Ref. 100). For example, transmission of the pathogen *Giardia lamblia* from animals to humans was linked to an outbreak of foodborne illness associated with consumption of contaminated produce (Ref. 109).

Proposed § 112.32(b)(3) would require that personnel wash hands thoroughly, including scrubbing with soap and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and that personnel dry hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices on specified occasions. Those specified occasions include before starting work; before putting on gloves; after using the toilet; upon return to the work station after any break or other absence from the work station; as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin; and at any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards. Under proposed § 112.32(b)(3), we would not expect workers to immediately stop work and wash their hands each time hands become soiled during the usual course of farm work with dirt or plant litter. However, we would expect workers to have sufficient training to recognize potential sources of hazards and to wash their hands when appropriate. We tentatively conclude that proposed § 112.32(b)(3) provides sufficient flexibility for operations to provide running water in a manner best suited to the conditions of use. For example, water can be supplied by a Public Water System, private well, or other source satisfying the requirements of § 112.44(a) through plumbed connections to building faucets (*e.g.,* inside a packing house) to supply running water throughout the facility. Alternatively, water supplied from sources above and used to fill clean, portable water containers suited to field use (such as a carboy, tank, water buffalo, or similar container) fitted with a valve, spout, or spigot such that water released passes over the hands also can provide adequate running water for washing hands. Under proposed § 112.44(a), with certain exceptions set forth in proposed § 112.45, you must test the quality of water used for hand washing during and after harvest to ensure that there is no detectable generic *E. coli* (see section V.E. of this document).

Workers often touch produce with their bare hands, and the produce covered by this rule would not necessarily have a ''kill step'' to adequately reduce pathogens that could be transmitted through bare-hand contact. Hand-washing, when done effectively, can eliminate both resident bacterial contamination (such as on the hands of a worker who may not realize he is ill or infected) and transient microbial contamination (such as bacteria, viruses, and parasites that gets onto hands through contact with the environment) (Ref. 110). As a result, hand-washing is a key control measure in preventing contamination of covered produce and food-contact surfaces (Ref. 26). The effectiveness of hand-washing is determined by multiple factors, including whether or not soap is used, the quality of water used, the duration of scrubbing and rinsing, and whether hands are dried. Soap serves as an emulsifier that enables dirt and oil to be suspended and washed off (Ref. 110). Rinsing hands without using soap, and not drying hands after washing, can promote the spread of microorganisms. For example, rinsing hands without using soap can loosen microorganisms without removing them, leaving the microorganisms more readily transferable to the next surface touched (Ref. 110). An investigation in follow-up to an outbreak of foodborne illness caused by *E. coli* O157:H7 in Florida found an association between illness and visits to fairs where visitors came in contact with animals, and found that persons who washed their hands with soap and water had a decreased likelihood of illness (Ref. 111). Drying hands is important because wet skin is more likely to transmit microorganisms than dry skin (Ref. 110). In addition, hand-drying has been demonstrated to remove bacteria from the hands and decrease ''touch-contact-associated bacterial transfer'' after hand-washing (Ref. 112). Proposed § 112.32(b)(3) does not prohibit use of hand sanitizers as a part of the hand washing process. However, our review of hand washing indicates that soap and water are far more effective than sanitizers in removing pathogens. The effectiveness of hand sanitizers has been shown to be highly dependent upon the removal of organic material from the hands prior to their use, as the presence of dirt, grease, or soil significantly reduces their effectiveness in eliminating bacteria on hands (Ref. 107).

Proposed § 112.32(b)(3) is similar to provisions in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96). Several differences exist between proposed § 112.32(b)(3) and analogous provisions in current §§ 110.10(b) and 111.10(b). For example, proposed

§ 112.32(b) would not specify, in addition to the requirements for hand washing, that hands also be sanitized if necessary to protect against microbial contamination, while both §§ 111.10(b) and 111.10(b) have such a requirement. We tentatively conclude that the circumstances where use of a hand sanitizer as an additional measure to reduce likelihood of contamination with pathogens would be limited on a farm. Hand sanitizers are less likely to be effective on a farm than in a processing plant, since growers' hands are more likely to get dirty during production on a farm and the resulting presence of organic material on the hands would impede the effectiveness of hand sanitizers (Ref. 113).

In addition, proposed § 112.32(b)(3)(v) would specifically require washing hands after touching animals, a requirement that is not included in current § 110. We are proposing this requirement here because contact with animals is more likely to happen on a farm. In addition, the National Association of State Public Health Veterinarians has recommend washing hands after touching animals as a protection against outbreaks of *E. coli* O157:H7, *Salmonella Enteritidis, Cryptosporidium parvum,* non-O157 STEC, *Salmonella typhimurium,* and *Campylobacter jejuni* (Ref. 111).

Proposed § 112.32(b)(3) also would repeat some of the characteristics of an adequate hand-washing facility specified in proposed § 112.130 (*i.e.,* soap, running water of specified microbial quality, and adequate drying devices). Currently, in our CGMP regulation for food facilities, § 110.37(e) identifies examples of how to achieve compliance with the requirements for an adequate hand-washing facility, but it does not repeat them in the requirement in § 110.10(b) regarding workers washing their hands. In proposed § 112.32(b)(3) (and in proposed § 112.130), we are proposing to identify specific characteristics of an adequate hand-washing facility because many of these facilities are likely to be in outdoor growing areas and be portable. Standard features that we have come to expect as a matter of course in a hand-washing facility in a building used for manufacturing/processing food may not be standard in a portable hand-washing facility. Moreover, the outdoor nature of many areas where covered activities take place naturally presents workers with situations where they will get dirt on their hands, and workers may be routinely handling food, with their bare hands, that will not be cooked to adequately reduce pathogens. Therefore, we believe it is appropriate to repeat these requirements in the proposed provisions for workers to wash their hands as well as in the proposed provisions directed to hand-washing facilities. We seek comment on the hand-washing proposals described above.

Proposed § 112.32(b)(4) would require that, if you choose to use gloves in handling covered produce or food-contact surfaces, you maintain gloves in an intact and sanitary condition, and that you replace such gloves when you are no longer able to do so. We are not proposing to require the use of gloves, but gloves are used in many operations to protect workers' hands. While gloves also provide a barrier that can reduce the potential for pathogens on workers' hands to contaminate covered produce, gloves themselves, whether re-usable or disposable, can transfer pathogens to covered produce if the gloves become contaminated (Ref. 26). If gloves are used in handling covered produce or food contact surfaces, requiring that such gloves be either in an intact and sanitary condition, or else be replaced, reduces the potential for the gloves to be a source of contamination for covered produce. Proposed § 112.32(b)(4) is similar to requirements in current §§ 110.10(b) and 111.10(b). Our GAPs Guide (Ref. 10), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99) and the Codex Code (Ref. 96) include specific provisions directed to the use of gloves. The AFDO Model Code (Ref. 20) and a marketing agreement (Ref. 31) direct farms to establish policies to ensure proper use of gloves. It has been reported that glove use can foster a ''false sense of security'' that can lead to less sanitary practices such as wearing the same pair of gloves for extended periods of time without cleaning them, or washing hands infrequently (Ref. 114). If your workers wear gloves, you should ensure that they know that wearing gloves in no way diminishes the importance of washing hands, and that gloves must be maintained and replaced, when necessary and appropriate.

Proposed § 112.33 would require that you take measures to prevent visitors from contaminating covered produce and food-contact surfaces with microorganisms of public health significance. Proposed § 112.33(a) would define a visitor as any person (other than personnel) who enters your covered farm with your permission. Proposed § 112.33(b) would require that you make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people, and that you take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. Proposed § 112.33(c) would require that you make toilet and hand-washing facilities accessible to visitors. In contrast to food processing facilities, on-farm visitors often enter areas where covered produce is grown and harvested, particularly on farms that offer consumers an opportunity to pick their own fruits and vegetables. As with workers, visitors can transmit pathogens to covered produce and food-contact surfaces. Thus, we are proposing to require that farms address the potential for visitors to contaminate covered produce, even though we have no similar requirements in regulations such as parts 110 and 111. Proposed § 112.33 is similar to provisions in our GAPS Guide (Ref. 10), the AFDO Model Code (Ref. 20), various produce industry guidelines (Ref. 89. Ref. 84. Ref. 99), a marketing agreement (Ref. 31), and the Codex Code (Ref. 96). A farm could comply with these proposed requirements by, for example, indicating the location of restrooms and hand-washing facilities accessible to visitors and clearly posting rules applicable to visitors where they are likely to be seen and read at the beginning of a visitor's visit, such as near the entrance or cash register at a ''pick-your-own'' farm operation.

E. Subpart E—Standards Directed to Agricultural Water

As proposed, subpart E discusses science-based minimum standards directed to agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed issues relevant to agricultural water. Several comments expressed concern that our proposed regulations could have an adverse effect upon or be in conflict with on-farm conservation or land management practices efforts; or that they could set standards for limiting all animal access to surface waters (*e.g.,* by fencing or other barrier) or prohibit vegetation (normally used to stabilize soil or for use as a natural water filter) surrounding surface water sources.

In developing the provisions in proposed part 112, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA (Ref. 115) to take into consideration conservation and environmental practice standards and policies established by those agencies. We recognize the importance of ensuring, to the extent possible, that our proposed provisions are compatible with existing conservation practices in the management of agricultural water systems. In proposed § 112.42(a)(1)–(5), we would require that you inspect your entire agricultural water system at the beginning of every growing season, focused on identifying conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. A similar (re)inspection would be required in proposed §§ 112.44(b) and (c) if the water you use for certain purposes does not meet the microbiological criteria described in those provisions. In each of these provisions, however, we do not describe specific inspection findings likely to adversely affect microbial water quality and relate them to specific required actions. For example, we do not propose that vegetation surrounding an on-farm pond be cut back and/or removed or that fencing must be used to prevent access to a pond by wildlife and domestic animals. We recognize that each farm, State, region, or produce commodity group may approach water management differently with respect to the likelihood of contamination of agricultural water and the use of specific conservation practices that may be appropriate or consistent with measures used to mitigate the likelihood of contamination. Practices used for one region or commodity may not be appropriate for others based upon historical experience. Under this proposed subpart, we would require that you address such issues only if they are reasonably likely to contribute to contamination of covered produce, and we would provide flexibility in the way in which you address any identified hazards, such that measures you implement to mitigate such hazards can be consistent with your current conservation practices. This approach allows you to put in place measures you deem most effective in addressing the potential for water contamination and to assess the effectiveness of those measures as they may be reflected in your microbial water quality data.

We also received a number of comments expressing concern about costs and associated burden related to testing of agricultural water, including pathogen testing, indicators, and frequency of testing. As described in section in the QAR, pathogen presence and distributions in the environment and water systems can be expected to be sporadic, with survival dependent on a multitude of factors. Thus, broad generalizations concerning their presence or persistence in water or on produce are problematic, and their detection difficult. Therefore, rather than testing for the presence or levels of various pathogenic microorganisms, we propose to use a microbial indicator as a monitoring measure to assess the potential for contamination. After considering various microbial indicators of water quality (see section V.E.2. of this document), we tentatively conclude that generic *Escherichia coli* (*E. coli*) is best suited for this purpose. It can be found in at least 90 percent of all human and animal feces (Ref. 116) and is most closely associated with incidents of fecal contamination (Ref. 107. Ref. 108. Ref. 109. Ref. 110. Ref. 108. Ref. 111. Ref. 112). There are multiple test methods, commercial kits, and formats available at relatively low cost, and the accuracy, precision, and sensitivity of these analytical testing options would meet the requirements in this proposed rule. Although the correlation between generic *E. coli* and fecal contamination is strong, as discussed in section V.E.2. of this document, generic *E. coli* does not always reliably predict the presence of pathogens despite fecal pollution being a known source of pathogenic microorganisms. This is explainable, however, considering the current understanding of pathogen occurrence and distribution described in the QAR and the taxonomic diversity of waterborne pathogens (*e.g.,* bacteria, viruses, and protists). Thus, generic *E. coli* monitoring serves as a measure to assess the potential for fecal contamination, not to directly predict the presence of pathogens.

Comments also emphasized that microbial testing should be performed at a frequency dependent upon the results of an assessment of the risks posed by your agricultural water system. We agree that the frequency should reflect the risk. In proposed § 112.45(a), with certain exceptions, we propose to require you to test water used for certain purposes at the beginning of each growing season, and every three months thereafter during the growing season. We tentatively conclude that this frequency would provide sufficient information regarding the microbial quality of your agricultural water. We are proposing in addition in § 112.45(b) that untreated surface waters must be tested more frequently than ground water sources because surface watersheds are subject to a greater number of external forces that shape their overall composition, chemistry, and microbial water quality (*e.g.,* erosion, run-off, dust, suspended sediments). We seek comment on our proposed approach.

A number of comments related to quantifying risks associated with the use of agricultural water as a function of water source, time of application, irrigation method, and commodity type. Our research shows that this is an extremely difficult task. In the QAR, we considered various factors relevant to produce production and harvesting, including water sources and use (See the QAR document). Some conclusions related to likelihood of produce contamination associated with water use can be drawn, although the relevance of these findings and whether they can be generalized across commodities, regions, and climates is not known. For example, Stine et al (2005) (Ref. 109) and Song *et al.* (2006) (Ref. 117) provide strong evidence that subsurface drip irrigation lowers the likelihood of waterborne contamination compared to furrow or overhead irrigation. These authors also suggest that proximity of the edible portion relative to water applied and surface texture of the edible portion play key roles in likelihood of contamination.

In addition, according to a WHO risk assessment (Ref. 118) of wastewater use in agriculture, pathogen (bacteria, protists, and viruses) die-off during the interval between last irrigation and consumption is approximately 1 log per day, although the rate varies with climatic conditions. Other measures that can be protective include cessation of watering, choice of irrigation method (localized irrigation—bubbler, drip, trickle is more protective than flood, furrow, or spray/sprinkler), and food preparation measures (washing) (Ref. 118). It is difficult to determine to what extent this assessment can be applied to water systems that are not based on wastewater use where high pathogen loads can be expected. Produce grown with water of significantly higher water quality continues to be implicated in disease outbreaks (Ref. 119). These outbreaks not only illustrate the challenge in assigning absolute risk reduction values to measures used in the mitigation of risk, but also the sporadic nature of pathogen occurrence and localized conditions leading to the persistence of pathogens in the environment.

A few comments recommended that equipment used to hold or convey water should be inspected to ensure that it is clean.

We agree that equipment used to hold or convey water should be maintained in a manner necessary to protect against contamination. In proposed 112.42(c), we propose to require that all agricultural water distribution systems must be adequately maintained as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system. In addition, in proposed 112.42(b), we propose to require that all agricultural water sources that are under the control of a covered farm (such as wells) must be adequately maintained by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

We seek comment on our proposals and approach related to agricultural water.

2. Water Quality Testing, Indicators, and Standards

In this subsection, we present a technical discussion of issues related to water quality such as testing samples, microbial quality indicators, and microbial quality standards. We discuss these issues in greater detail in this subsection to further support the provisions proposed below related to water quality testing and microbial indicators.

A fundamental component in assessing the adequacy of water for its intended use is a routine sampling and microbial testing program (Ref. 120. Ref. 29). Water sampling and testing allows for informed decisions regarding the management of water use, such as choosing a water source and combining that selection with, for example, the irrigation method for a specific commodity or time period prior to harvest. Testing for microbial quality of water can identify possible fecal contamination at the water source or in a section of its distribution system (*e.g.,* line break). Additionally, regular testing data may be used to identify seasonal (or other) trends and highlight areas of the system that may require attention. For example, regular testing results may show that periodic increases in indicator organisms are correlated with precipitation levels or suspended sediments in surface waters, providing useful information about when and how that water source can be safely used.

Microbial water quality testing can be performed using a variety of methods that have been validated for water testing. A key element of any testing program is determining the indicator organism or specific pathogen(s) and the frequency of testing. The sensitivity of the method is also important, although most test methods available today have sensitivities that match or exceed requirements for EPA drinking water and FDA bottled water standards.

Surface water quality and pathogen monitoring studies reported in the literature often quantify indicator organisms or pathogens on a monthly basis. However, most studies do not specifically address the impact of water quality on produce safety (Ref. 115. Ref. 116. Ref. 117. Ref. 118). A lack of consensus among the different recommendations and approaches underscores the complexity and uncertainty in water quality sampling and testing strategies. Nevertheless, a vast majority of studies that address frequency of testing recommend that surface water sources should be sampled more frequently than ground water sources (Ref. 121).

Two key determinants of an appropriate testing frequency emerge from this information: (1) Variability of the water source and (2) the extent to which it can be protected. The discussion above suggests that water obtained from a public water source is least likely to be a vehicle for pathogen contamination of produce, followed by water obtained from deep underground aquifers, shallow wells, and surface waters, in that order. This is consistent with findings reported in the literature (Ref. 122. Ref. 29). For purposes of defining likelihood of contamination, we further divide surface water into two types, based on the potential for contamination (through runoff), and the degree to which potential contamination can be recognized and controlled (*i.e.,* (1) surface waters where runoff is difficult to recognize and control because of the size of the watershed (*e.g.,* river or lake) and (2) surface waters where runoff can be easily detected and which can be managed so as to protect them from runoff (*e.g.,* on-farm reservoir or pond)). Runoff is used here in differentiating the likelihood of contamination of surface water because it has the potential to carry pathogens and is known to mobilize pathogens from sediment reservoirs to the water column (Ref. 117. Ref. 120. Ref. 121. Ref. 122. Ref. 123) as well as carry pathogens to the surface water system from sources such as failing septic systems and deposited animal feces (Ref. 123. Ref. 124).

a. Microbiological Indicators of Water Quality

A primary consideration in establishing a microbiological water quality testing program is the choice of target organism(s). Two general approaches are commonly used: Test for the presence of an indicator organism(s) that may signal the presence of pathogens or test for pathogens themselves. In the United States, bacterial indicators have a long history of being used to demonstrate the safety of drinking water and adequacy of its treatment at the source. They have also been used to monitor the status of drinking water in distribution systems and determine if surface waters are microbiologically safe for recreational use (*e.g.,* swimming) and shellfish harvest (Ref. 123).

Bacterial fecal indicators are non-pathogenic microorganisms that are commonly found in the intestines of warm-blooded animals that are easily isolated and quantified as a measure of fecal contamination and potential for enteric pathogens. Desired characteristics for effective indicator organisms include: Ease of detection; being present only when fecal contamination or pathogens are present; and, being in numbers that correlate with the amount of contamination, numbers of pathogens and risk of illness. Survival times of indicator organisms in sediments and in water should be equal (or greater) to those for pathogens and their detection should be accomplished by simple, rapid methods at low cost. Indicator microorganisms are widely used in water quality testing because of their broad utility across many types of water but no single indicator that is universally accepted (Ref. 123).

Pathogen detection has the obvious advantage of directly targeting microorganisms in water that are a risk to public health. However, sampling water for pathogens may present additional challenges, including larger sample sizes to facilitate detection, inherently higher costs, and the wide array of potential target pathogens (*i.e.,* the presence or absence of one pathogen may not predict for the presence or absence of other pathogens).

A number of indicator microorganisms have been used to predict the presence of pathogens in water, with varying degrees of success. These include total coliforms, fecal coliforms, enterococci, generic *E. coli,*

and coliphages. However, their presence does not always signal the presence of pathogens and the absence in their detection is not assurance that pathogens are absent (Ref. 126. Ref. 127. Ref. 128. Ref. 129. Ref. 130).

Consequently, Gerba (2009) (Ref. 120) suggested indicators be defined by a purpose for which they are better suited instead as an indicator for pathogens. For example, efficacy of treatment (*e.g.,* public water systems) or integrity in manufacturing processes (*e.g.,* bottled water) can be effectively monitored by total coliforms because these environmental bacteria are not expected to survive the treatment conditions or be introduced during the manufacturing process. Their presence in treated municipal water or in bottled water may signal an inadequate treatment or deficient manufacturing step meriting investigation and subsequent corrective action to resolve the problems identified. Another example is using fecal indicator bacteria (*e.g.,* enterococci or generic *E. coli*) to assess the risk of gastrointestinal illness (or other adverse health conditions) in marine and freshwater swimmers, because their presence is statistically correlated to adverse health outcomes in these groups (Ref. 119. Ref. 120). Generic *E. coli* alone, as an easily distinguishable member of the fecal coliform group, is more likely than the fecal coliform group as a whole to indicate fecal pollution (Ref. 120). Used in this way, indicator organisms are not used specifically to predict the presence of pathogens, but are useful predictors of undesirable conditions (*e.g.,* ineffective treatment, defective manufacturing process, presence of fecal material).

Total coliforms have frequently been used to assess water quality of several different types of natural waters (*e.g.,* freshwater and marine) but their use for this purpose has decreased recently as they have been found to be present in natural water both because of fecal contamination and as natural environmental inhabitants. They are regularly isolated from soil, plants, vegetables, and effluents from agricultural and food industries but their presence does not reliably signal a fecal contamination event (Ref. 131. Ref. 112). Fecal coliforms share a similar problem. Fecal coliforms are coliforms that are capable of growth at higher temperatures, conditions similar to those which can be found in the mammalian gut. However, some of its members (*e.g.,* Klebsiella, Citrobacter, Enterobacter spp.) can normally be found outside the intestine including soil, water, vegetation, fresh vegetables, silage, insects, and many others (Ref. 124) and there is ample evidence that they can grow and multiply there (Ref. 132. Ref. 133. Ref. 114. Ref. 123). This makes using fecal coliforms as indicators for fecal contamination problematic, as it would be difficult to separate increases in their numbers due to natural forces (*e.g.,* precipitation, erosion, wind, temperature) from increases due to fecal contamination events.

Generic *E. coli* is a member of both the coliform and fecal coliform groups but has been shown to more consistently be associated with fecal contamination than other indicators (Ref. 134. Ref. 135. Ref. 133. Ref. 136. Ref. 137. Ref. 138. Ref. 112). It can be found in at least 90 percent of all human and animal feces (Ref. 108) (Ref. 116) where it persists, more than other transient fecal *coli*forms (Ref. 125. Ref. 124). While its association with fecal contamination is very strong, it has also been isolated from environments with no apparent fecal contamination, including tropical watersheds (Ref. 126) and paper mill effluents (Ref. 127). Outside of these findings, reports of generic *E. coli* growth and proliferation outside the gut (*e.g.,* in water) are generally rare. Generic *E. coli* demonstrates variable survival times in water but may only persist from 4 to 12 weeks at 15–18 degrees Celsius (Ref. 116).

Generic *E. coli* has an extensive history of use as an indicator of fecal contamination and is considered the best indicator for monitoring water quality (Ref. 119). Its detection and enumeration can be performed using a variety of commercial products at relatively low cost. However, its ability to signal fecal contamination events is dependent upon sampling frequency and location relative to the source of contamination. Thus, instances of non-detection are not considered confirmation of the absence of fecal contamination because sampling frequency may not be adequate to detect events occurring over short periods of time. Sampling results can only be considered snapshots of water quality over time. Moreover, the fate and transport of generic *E. coli* in watersheds may be different than other fecal constituents in response to localized conditions (*e.g.,* sunlight, temperature) (Ref. 128. Ref. 129. Ref. 130).

One challenge in using indicator organisms to predict water quality is correlating information concerning their numbers to the presence or absence of pathogens (as compared to the presence or absence of fecal material). Although generic *E. coli* is recognized as a good indicator of fecal contamination, pathogens are not always present in that fecal material because their distribution and persistence is sporadic. As a consequence, the record of generic *E. coli* as a predictor of pathogens is mixed. The Canadian Federal-Provincial-Territorial Committee on Drinking Water states generic *E. coli* is unsatisfactory in predicting the presence of *Giardia, Cryptosporidium,* and enteric viruses (Ref. 119. Ref. 124) and Horman *et al.* 2004 (Ref. 131) found poor correlation between generic *E. coli* and the presence of pathogens (*Campylobacter* spp., *Giardia* spp., *Cryptosporidium* spp., and noroviruses) in Finnish surface waters. However, they did conclude that the absence of generic *E. coli* was a very strong predictor for the absence of pathogens. Duris et al (2009) (Ref. 132) found generic *E. coli* inconsistently correlated to genetic markers for generic *E. coli* O157 in Michigan and Indiana river water but suggested the relationship could be strengthened by increased sample size. Alternately, Wilkes *et al.,* 2009 (Ref. 133) reported generic *E. coli* concentrations were the best indicator of pathogens (*E. coli* O157:H7, *Salmonella* spp., *Campylobacter* spp, *Giardia* and *Cryptosporidium*) presence/absence in Canadian watersheds. Others have noted that generic *E. coli* has a better record as an indicator for *Salmonella* than for *E. coli* O157:H7 (Ref. 134). Review of these studies illustrates the complexity of possible interactions between indicators and pathogens in water, and their potential for separate fates within those systems.

Studies relating indicators, pathogens, and the risks associated with produce consumption are few and are complicated by the relationships described above. Different survival profiles between indicators and pathogens on produce may also affect risk. The World Heath Organization (Ref. 118) proposed a set of pathogen reduction measures that can be used alone or in combination to achieve a 6–7 log pathogen reduction they determined necessary to meet health-based targets. To verify the effectiveness of the measures, they recommend monitoring generic *E. coli* levels in treatment effluents and in crops at harvest. They noted that field pathogen die-off is variable (0.5–2 log per day), dependent on temperature, sunlight, crop type, time, and other factors.

Produce contamination events that occur during growing, harvesting, packing, or holding on farm are generally thought to occur intermittently and at low doses. As a result, the detection of human

pathogens in contaminated produce using available testing methodologies remains an arduous process. It is impractical to test 100% of the product; therefore sampling plans to collect a statistically significant subset must be devised. Unfortunately, although such testing has in the past prevented some contaminated product from entering the market when pathogens are found, it is also very possible that testing can entirely miss a point contamination, thus it cannot provide a litmus test for food safety because the sample size needed to detect low dose, low frequency, and non-uniformly distributed contamination is impractically large (Ref. 135). In addition, microbial testing can only detect the pathogens the analytical procedures are designed to detect, and we tend to only test for pathogens known to be of concern. Considering the range of potential pathogens, these are significant limitations.

b. Microbial Water Quality Standards

The lack of sufficient information to support a pathogen-based microbiological standard for water used in the production of produce has led to the adoption of the generic *E. coli* component of the U.S. EPA recreational water standards (for frequently used beaches) by some industry groups (Ref. 44. Ref. 31). The EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136). Generic *E. coli* was found to be a good predictor of swimming associated illness in freshwater and the EPA recommended criteria include a geometric mean of 126 CFU per 100 ml and a single sample maximum for designated beach areas of 235 CFU per 100 ml (Ref. 136). British Columbia, Canada has announced their intention to use a similar approach in setting generic *E. coli* criteria for irrigation water used on produce consumed raw. Their irrigation criteria (less than or equal to 77 CFU per 100 ml geometric mean) are the same as and were derived from those used for primary-contact recreation (Ref. 137). See section V.E. of this document for additional discussion of this issue.

The U.S. EPA criteria were developed from epidemiological studies of beach areas subject to point source fecal contamination rather than non-point source contamination (*e.g.,* birds, agricultural and livestock runoff). Non-point sources may also influence the quality of agricultural water. Further, adverse health outcomes as a consequence of immersion while swimming in contaminated water may be different from those as a result of eating produce irrigated with contaminated water. The routes of infection and pathogen mortality rates are different in each environment.

Based upon a WHO analysis of tolerable risk for irrigation water, the minimum microbial quality for water used on root crops that are eaten raw is 1,000 CFU generic E. coli per 100 ml (10,000 CFU generic E. coli per 100 ml in leaf crops) (Ref. 120. Ref. 118). According to the WHO analysis, using water of this microbial quality is dependent upon a 2 log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1 log reduction attributed to washing prior to consumption. This analysis recognizes the variable nature of die-off values, ranging from 0.5–2.0 log per day (Ref. 118). The WHO analysis considers the need for a four log reduction through dilution, die-off, or treatment between the levels of generic E.coli in raw sewage (well represented in sewage by fecal coliform levels) and the levels in irrigation water used on root crops that are eaten raw (3 log for leaf crops), in addition to the 3 log reduction discussed above.

3. Proposed Requirements

a. General Requirement

Proposed § 112.41 would establish the requirement that all agricultural water must be safe and of adequate sanitary quality for its intended use. The principle of ''safe and of adequate sanitary quality for its intended use'' contains elements related both to the quality of the source water used and the activity, practice, or use of the water. Uses vary significantly, including: Crop irrigation (using various direct water application methods); crop protection sprays; produce cooling water; dump tank water; water used to clean packing materials, equipment, tools and buildings; and hand washing water. The way in which water is used for different commodities and agricultural practices can determine how effectively pathogens that may be present are transmitted to produce.

Comparing the probability of contamination of covered produce associated with key practices at different stages of production and across a range of commodities, the interrelatedness of these factors becomes apparent. The QAR shows that the likelihood of contamination associated with indirect water use for irrigation is relatively low compared to irrigation water that directly contacts produce (Ref. 2). Therefore, in Section V.A.2.b (Definitions), we propose to define ''agricultural water'' to mean water used in covered activities on covered produce, where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). As we propose in § 112.3(c), ''covered produce'' refers to the harvestable or harvested portion of the crop. As proposed, ''agricultural water'' does not include indirect water application methods used during growing. For example, generally, the water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop. As another example, generally, the water used for overhead spray irrigation of romaine lettuce would be considered agricultural water because the water is likely to contact the harvestable portion of the crop. We are proposing to distinguish between water that is intended to, or is likely to, contact covered produce or food-contact surfaces (*e.g.,* direct water application method irrigation water) and water that is not intended to, or is not likely to, contact covered produce or food-contact surfaces based on the relative likelihood of contamination from water that contacts covered produce and the need for measures to minimize such likelihood.

If finalized as proposed, indirect water application methods would not be subject to the requirements of this rule. While indirectly applied water is unlikely to contact produce or food-contact surfaces, we recognize that it presents the possibility of produce contamination. For example, use of contaminated water in drip or furrow irrigation may still serve as a vehicle for bringing contaminants into the growing environment which may potentially be transferred to produce by rain splash, workers, or equipment; use of contaminated water for dust abatement on farm roads may also be transferred to produce by run-off, rain splash, workers, or equipment.

Indirect water application methods would remain subject to Section 402(a)(4) of the FD&C Act. That is, indirect water application may

adulterate produce if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Moreover, if a pathogen is detected in or on produce, such produce would be considered adulterated under Sections 402(a)(1) of the FD&C Act, in that it contains a poisonous or deleterious substance which may render it injurious to health. Therefore, we tentatively conclude that indirect water application methods do not need to be covered within the scope of ''agricultural water'' for the purposes of this rule.

We ask for comment on the limited scope of ''agricultural water'' to only water that is intended to, or likely to contact covered produce or food-contact surfaces. We also seek comment on its resulting effect on the applicability of the general requirement in proposed § 112.41 that agricultural water must be safe and of adequate sanitary quality for its intended use, to only water that is intended to, or likely to, contact covered produce or food-contact surfaces. Water that is not safe or of adequate sanitary quality for its intended use may lead to contamination of covered produce, even where the water use is indirect. We have previously recommended measures such as indirect water use when water quality is poor or unknown as a measure to minimize risk (Ref GAPs Guide). Considering the FD&C Act would still apply to such uses, and that there is a lower likelihood of contamination of produce by indirect water use, is there a need to subject indirect water use, including water used for dust abatement, to the general requirement in proposed § 112.41? We welcome comment on this approach, as well as other actions that have been found to be effective through practice and experience.

We also considered proposing some requirements for water that is used during growing, but which does not contact the harvestable portion of covered produce. For example, water that did not contact produce would not have been subject to any testing requirement, although we considered requiring this water and all agricultural water to be of safe and adequate sanitary quality for its intended use (proposed § 112.41). We also considered requiring indirect water to comply with proposed § 112.42(a) (sanitary survey) and § 112.42(b) through (d) (adequately maintaining water sources under your control). If we did include both direct and indirect water use in the definition of ''agricultural water'' in the final rule, which of the proposed requirements for agricultural water described in section V.E. of this document would (or would not) be appropriate for indirect water use? Are there other factors that we should consider? In every application of water, careful consideration should be given to what you know about the water's quality at its source, the impact your distribution system may have on the water quality, and when or how that water is to be used. For example, water that contains *Salmonella* would not be safe or of adequate sanitary quality for its intended use when used in a postharvest dump tank for tomatoes. *Salmonella* is a food safety hazard that is well-documented to present a risk of severe adverse health consequences or death, and tomatoes can become contaminated by water containing *Salmonella* (Ref. 138. Ref. 139. Ref. 140). As another example, when the surface water (*e.g.,* river) that you use for crop irrigation using a direct application method has a noticeable decrease in quality due to an upstream event like the failure of a waste water treatment plant, resulting in the accidental discharge of untreated municipal sewage into the river, your water source would not be safe or of adequate sanitary quality for its intended use until the discharge is over and the water has been tested because the incompletely treated sewage in the discharge is likely to contain pathogenic microorganisms that could compromise the safety of irrigated covered produce.

The most frequently used irrigation methods include overhead, surface and subsurface drip, furrow, flood, and seep irrigation (Ref. 29). These practices may be commodity-specific and choices may be limited by the availability of different water sources, crop needs, climate, precipitation levels, or regional practices. Each irrigation method presents a different likelihood of contamination, independent of the water source and its application to a particular commodity. For example, the likelihood of produce contamination may be reduced if irrigation water is delivered by subsurface drip irrigation compared to using the same water to irrigate by overhead spray (Ref. 141. Ref. 122). Researchers also concluded that both the physical properties of the edible portion of the crop, such as surface texture, and the location of the edible portion of the plant in relation to irrigation water played significant roles in contamination (Ref. 130). As discussed in the QAR, the timing of irrigation water application also plays a role in minimizing the persistence of contamination. For example, water containing elevated generic *E. coli* used in overhead irrigation shortly before harvest may increase the likelihood of covered produce being contaminated with the pathogen at harvest, but the same water could safely be used to establish a crop and throughout the majority of the growing season because, as discussed in the QAR, pathogens die-off over time on the surface of produce. Water used for washing hands during and after harvest, sprout irrigation, directly contacting produce during or after harvest (such as in washing and cooling, or to make ice that directly contacts produce), making treated agricultural tea, and water or ice that will contact food contact surfaces that contact covered produce presents an even greater likelihood of microbial contamination of covered produce (Ref. 131. Ref. 132). Waterborne pathogens can be transferred to covered produce with little opportunity for die-off if contaminated water is used for hand washing during or after harvest, or in harvest, packing or holding activities where it directly contacts produce or surfaces that contact produce and, therefore, it is important to ensure that the water is safe and of adequate sanitary quality for such uses. Moreover, the high nutrient, high moisture conditions inherent to sprout production and agricultural teas not only support pathogen survival but are also conducive to their amplification if present (Ref. 142. Ref. 16). Again, the selection of a water source for these uses must ensure that the water is safe and of adequate sanitary quality for that use.

b. Measures Regarding Agricultural Water Sources and Distribution Systems

Proposed § 112.42 would establish the measures that you must take with respect to agricultural water sources, water distribution systems, and pooling of water.

Proposed § 112.42(a) would establish that at the beginning of a growing season, you must inspect the entire agricultural water system under your control (including water source, water distribution system, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

(1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent or nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

Human pathogens can enter an agricultural water system anywhere from its source to point of use. Central to the prevention of pathogen contamination of agricultural water is an inspection of water source and the components of the distribution system to identify potential routes of contamination. Inspections of water sources and components of its distribution system are recommended by government and industry references (Ref. 10. Ref. 20. Ref. 45. Ref. 44).

Generally, inspection of the agricultural water system under your control beginning at the water system source is the first opportunity for ensuring that it will deliver water that is safe and of adequate sanitary quality for its intended use. Inspection of your water source provides an opportunity to identify and characterize activities and situations that may lead to contamination of your agricultural water. Further, inspection results provide you with historical knowledge of your water sources, their quality, and factors that may affect their quality (Ref. 31). Inspection of the water source and any equipment used to obtain the water from the source (*e.g.,* well head, pumps, pipes) can ensure that the water that enters the distribution system is suitable for its intended use.

Proposed § 112.42(a)(1) requires you to consider the nature of your agricultural water sources to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. As discussed in the QAR, ground water which is often believed to be pathogen free can be contaminated. Ground water can also be compromised and its water quality degraded if wells are improperly constructed, poorly maintained, or improperly located (*e.g.,* near areas of extensive livestock production or fields where manure is applied (Ref. 143. Ref. 144. Ref. 122). U.S. water systems using ground water as source waters for drinking must operate in compliance with the U.S. EPA Ground water Rule (GWR) (40 CFR parts 141 and 142) to protect against illness from waterborne pathogens in ground water. However, the GWR does not address private wells because they are not under the jurisdiction of the Safe Drinking Water Act and are therefore not subject to EPA regulation. Thus, water quality and survey data on ground water used for agriculture are not publicly available. By their nature, surface waters are open systems, subject to the influence of various environmental factors that can impact the safety of the water. For example, increased precipitation levels, storm events, or wind may result in a spike in water turbidity, due to redistribution of sediments. We tentatively conclude that there exists significant potential for contamination of ground and surface waters and, therefore, we propose to require you to include both ground and surface water sources in your inspection of your agricultural water systems. We seek comment on this tentative conclusion and associated proposals.

Proposed § 112.42(a)(2) requires you to consider the extent to which you have control over your agricultural water source to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces. You may have more control over your ground water source (well) if it draws water from an aquifer beneath your property and which you protect from the influence of surface activities. You would likely have less control if your well is located near a concentrated animal feeding operation or is influenced by surface water (*e.g.,* a shallow well). You may have greater access to and control of on-farm surface water sources such as impoundments, catches, and ponds, than you would for flowing surface waters that only course through but do not originate on your land.

Proposed § 112.42(a)(3) requires you to consider the degree of protection of each agricultural water source. Examples of protection for water sources include covers, containments, or fencing that exclude domesticated animals or other possible sources of contamination from the water source or earthen berms or other barriers that help minimize the influence of runoff on the water source.

Proposed § 112.42(a)(4) requires you to consider the use of adjacent or nearby land. Agricultural water may be affected by upstream agricultural practices and runoff from those operations into surface water sources that you use. For example, an upstream alfalfa grower may apply raw manure as a soil amendment, and irrigation water runoff from that field may flow into your agricultural surface water source. While you may have little or no control of other agricultural water user practices, this proposed requirement to consider those nearby uses of which you are aware will help you determine appropriate and safe use of that water source.

Proposed § 112.42(a)(5) requires you to consider the likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm. For example, if you use water from a river and are downstream from a waste water treatment plant that discharges into that river, this provision would require you to consider the likelihood that the wastewater treatment plant introduces hazards into the water before it reaches your farm. For example, you would consider the likelihood of accidental discharge of untreated municipal sewage into the river.

Proposed § 112.42(b) would require that you adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances. Regular maintenance of your water sources is imperative to ensure the continued safety of your water. Maintenance of on-farm water sources may include upkeep and repair of berms, pipes, liners, or any structural elements, that are used to protect the source. Properly maintaining a well includes conducting wellhead inspections, during which time you check the condition of the well covering, casing, and cap to make sure all are in good repair, leaving no cracks or other entry points for potential contaminants. Properly maintaining a storage tank includes cleaning the interior surfaces of all rust scale, paint scale, dirt, and bio-film forming growths and inspecting exterior surfaces for corrosion which may become a route of contamination (Ref. 31). Properly maintaining a farm pond that is used for irrigation using a direct application method, with respect to keeping it free from domesticated animals, could mean fencing the pond if you keep domesticated animals in the area such that they would otherwise have access to the pond. On the other hand, if you treat the water before use in this way, you may not need to take steps to prevent access of the domesticated animals to the pond. This proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue,

hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct).

Proposed § 112.42(c) would require that you adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system. Regular maintenance of your agricultural water distribution system can be performed in conjunction with inspections and cleaning, as applicable. If not regularly maintained, portions of a water distribution system may fail, corrode, collect debris, or otherwise become a source of contamination. For agricultural water distribution system components that are underground, it would be important to look for signs of erosion or wet soil areas, as they may indicate a damaged underground component requiring further inspection and maintenance (Ref. 145).

Proposed § 112.42(d) would establish that you must immediately discontinue use of a source of agricultural water and/or its distribution system, and not use the water source and/or its distribution system when you have determined or have reason to believe that your agricultural water is not safe and of adequate sanitary quality for its intended use, until you either: (1) Re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and test the water to determine if your changes were effective and to ensure that your agricultural water is safe and of adequate sanitary quality for its intended use; or (2) treat the water in accordance with the requirements of § 112.43. Using agricultural water that is not safe or of adequate sanitary quality for its intended use may lead to contamination of covered produce. Lapses in sanitary quality of water can occur in any segment of a water system, from source to point of use. For example, if you find that water contains *Salmonella* at the point where it would be used in a dump tank for tomatoes, it would not be safe or of adequate sanitary quality for that intended use. As another example, your water would not be considered safe or of adequate sanitary quality for its intended use if you found detectable generic *E. coli* in a 100 ml water sample you obtained at the point where the agricultural water is used for washing produce as described in proposed § 112.44(a). Similarly, your water would not be considered safe or of adequate sanitary quality if you found that test results exceeded 235 CFU per 100 ml generic *E. coli* in a water sample you obtained from water used to overhead irrigate lettuce (a direct application method) as provided in proposed § 112.44(c). We seek comment on these proposed thresholds.

Under this proposed provision in § 112.42(d)(1), for example, you would review your previous inspection results for the affected portion of your agricultural water system and compare those results to conditions you currently observe. You would identify changes likely to have an impact on the quality of water (*e.g.,* evidence of runoff, animal intrusion, suspended sedimentation, changes in adjacent land use) or any lapses in your procedures (*e.g.,* outdated well inspection, break in the water treatment schedule). You would test the water after you make changes you find necessary during your inspection. Under the proposed provision in § 112.42(d)(2), you could instead choose to treat your water in accordance with the requirements of § 112.43 to ensure its safety. We tentatively conclude that the measures proposed in § 112.42(d) are necessary and adequate to address deficiencies that may exist in your water management system and practices so that your agricultural water does not serve as a source of contamination to covered produce. We welcome comment on this approach, as well as other actions that have been found to be effective through practice and experience.

Proposed § 112.42(e) would establish that, as necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of pooling of water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground, or using an alternative irrigation method. Pooling may occur if excessive water is applied to a crop, especially in areas of poor drainage. Pooled water that remains for extended periods of time has been shown to increase likelihood of contamination (Ref. 10. Ref. 45). Further, if pooled water is in close proximity to the crop, it may serve as an attractant for pests. Mounding soil, staking, subsoil drip irrigation, drip tape or plasticulture (use of agricultural plastics) are methods that are used to reduce the potential for pooling or to separate the pooled water from the covered produce. We acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature, which are temporary and occur in the normal course of irrigation practices, are not reasonably likely to contribute to the contamination of covered produce. We are not suggesting that it will always be possible to eliminate pooling. Avoiding pooling by careful control of irrigation is ideal; however, events such as rainfall or irrigation malfunction may sometimes make pooling inevitable. In those cases, the proposed requirement would require farms to take steps to protect covered produce from contamination that may build in the pooled water.

c. Requirements for Treating Agricultural Water

Water treatment is an effective means of decreasing the number of waterborne outbreaks in sources of drinking water (Ref. 146). However, treatments that are inadequate or improperly applied, interrupted, or intermittent have been associated with waterborne disease outbreaks (Ref. 146). Failures in treatment systems are largely attributed to suboptimal particle removal and treatment malfunction (Ref. 147). For this reason, when treating water, it is important to monitor the treatment parameters to ensure the treatment is delivered in an efficacious manner. Monitoring treatment can be performed in lieu of microbial water quality monitoring, if under the intended conditions of the treatment, the water is rendered safe and of adequate sanitary quality for its intended use. Many operations choose to perform microbial water quality testing in addition to monitoring the water treatment as a further assurance of treatment effectiveness (Ref. 148).

Proposed § 112.43 would establish requirements related to treatment of agricultural water. Specifically, proposed § 112.43(a) would require that you must treat any agricultural water that you use (such as with an EPA-registered antimicrobial pesticide product) if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, whereas proposed § 112.43(b) would require that any method you use to treat agricultural water to satisfy this requirement in paragraph § 112.43(a) must be effective to make the water safe and of adequate sanitary quality for its intended use. In addition, proposed § 112.43(c) would require you to: (1) Deliver any treatment

of agricultural water required by § 112.43(a) in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use; and (2) monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

If you choose to use water that is not safe or of adequate sanitary quality for its intended use, the water must be treated before it is put to such use to minimize the likelihood for contamination. For example, treating agricultural water with antimicrobial compounds can be an effective means to eliminate pathogens if done properly, including under conditions that ensure the effectiveness of the active ingredient (Ref. 149. Ref. 150). Any chemicals used in the treatment of water would require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used. We note, however, that at the present time, no such registration for chemical treatment of irrigation water exists. We anticipate that the proposed delayed implementation period for water quality testing (see section IV.K. of the document) would provide industry adequate time to address such issues. We seek comment on this issue.

To ensure water treatment is delivered in an effective manner, monitoring the conditions of treatment is also essential. An effective monitoring program would measure the level of active compound as well as those factors that may affect its activity, such as pH, temperature, and contact time. For example, monitoring water treated with hypochlorite in an orange postharvest wash would include, at a minimum, monitoring the level of active antimicrobial (free available chlorine) and pH, since it is known that hypochlorite activity is reduced both by organic material (*e.g.,* soil, plant debris) and pH values outside its effective range (pH 6.0–7.5) (Ref. 149. Ref. 150). The concentration of active disinfectant and pH must be adjusted, as necessary, taking into account variations in water quality in order to maintain the effectiveness of the treatment. In addition, the frequency in which you monitor agricultural water treatment must be adequate to ensure that the conditions for proper treatment are consistently met and adjusted, as necessary, to result in water that is safe and adequate for its intended use. Research has shown that in other settings, monitoring of physical parameters, such as temperature, pH and disinfectant concentration, can be done in real-time and in an inexpensive, automated manner, facilitating good control of the process (Ref. 149). As a verification that the treatment process, monitored in accordance with the proposed requirements of § 112.43(c)(2), is effective in achieving a certain microbial standard (*e.g.,* no detectable generic *E. coli* in 100 ml of water), you may chose to perform periodic microbiological analysis of the treated agricultural water. We are not proposing at this time that treated water must be tested in this manner because we believe that the effectiveness of various treatment processes is well understood. However, we encourage farms to perform such testing to provide further assurance of the effectiveness of their treatment under the specific conditions that exist on their farm. We seek comment on this issue.

d. Testing and Frequency of Testing of Agricultural Water

Proposed § 112.44 would establish requirements related to testing of agricultural water and subsequent actions based on the test results. Specifically, proposed § 112.44(a) would require that you test the quality of agricultural water according to the requirements in § 112.45 using a quantitative, or presence-absence method of analysis provided in subpart N to ensure there is no detectable generic *E. coli* in 100 ml agricultural water when it is:

(1) Used as sprout irrigation water;

(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;

(3) Used to make a treated agricultural tea;

(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or

(5) Used for washing hands during and after harvest activities.

We seek comment on the appropriateness of these proposed categories in which testing would be required.

Proposed § 112.44(b) would require that if you find that there is any detectable generic *E. coli* in 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in § 112.44(a). Before you may use the water source and/or distribution system again for the uses described in § 112.44(a), you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the requirements of § 112.44(a); or treat the water in accordance with the requirements of § 112.43.

We reviewed the most widely used indicator(s) or indicator groups for their potential in assessing the microbial quality of water used for purposes described in proposed § 112.44(a) and all other uses of agricultural water as described in section V.E.2 of this document. We considered total coliforms and fecal coliforms as indicators of fecal contamination but determined that neither of them can serve as reliable indicators of a fecal contamination event (Ref. 124. Ref. 119. Ref. 151. Ref. 152). *Generic E. coli* is a member of both the coliform and fecal coliform groups but, unlike some members of those groups, it has been shown using various detection methods to be the only coliform consistently associated with fecal contamination (Ref. 132. Ref. 133. Ref. 134. Ref. 135. Ref. 136. Ref. 137. Ref. 108). Generic *E. coli* has an extensive history and support for use as an indicator of fecal contamination. Recently, it has emerged as the preferred indicator for monitoring water quality, not only because of the problems with other groups noted above, but also due to the development of superior methods of detection with greater accuracy, sensitivity, and simplicity over those previously used (Ref. 119). Despite widespread use and support for generic *E. coli* as an indicator of fecal contamination, its ability to signal contamination events is not without challenges. Sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Ref. 133. Ref. 143. Ref. 153. Ref. 131). Thus, non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. Further, the fate and transport of generic *E. coli* takes different paths in different watersheds, and reservoirs have been identified, particularly sediments, where they may escape detection in the water column (Ref. 128. Ref. 129. Ref. 130. Ref. 154). Nevertheless, based on our review of the literature, we

tentatively conclude that generic *E. coli* serves as the most appropriate microbial indicator of fecal contamination of water at this time and, therefore, we propose to use a microbial standard of no detectable generic *E. coli* in 100 ml agricultural water when it is for the intended uses listed in § 112.44(a). We seek comment on our selection of this indicator.

As discussed in the QAR, water used for the purposes listed in proposed § 112.44(a) has the potential to serve as a vehicle of pathogen contamination by direct contact with covered produce. Water used in sprout production must be free of fecal contamination because the conditions under which sprouted seeds are produced (warm, moist, nutrient-rich environment for extended period of time) are conducive to pathogen multiplication (Ref. 14). As discussed in section I.A. of this document, outbreaks associated with sprouted seeds are well documented; *Salmonella* and *E. coli* O157:H7 have been the major causes of sprout-associated outbreaks (Ref. 14). Similarly, the conditions under which agricultural tea is produced (moist and nutrient-rich) are similar in that they support the multiplication of pathogens, if present (Ref. 142). Even a low number of pathogens introduced into or onto covered produce through contaminated water could rapidly increase to levels that could present risk of serious adverse health consequences or death to those who consume the covered produce for which the tea was used. Further, water that is used in direct contact with produce or food contact surfaces, or in making ice that directly contacts produce or food contact surfaces, must also be free of fecal contamination and pathogens. These water applications normally occur during or shortly after harvest, leaving only a relatively short period of time before consumption for the environmental factors that drive pathogen die-off to exercise a significant effect (see the QAR). In addition, we propose to apply the microbial standard in proposed § 112.44(a) to agricultural water that is intended for use in washing hands during harvesting, packing, and holding activities, where there is little opportunity for microbial die-off prior to consumption. Hands that contact produce during and after harvest must be free of microbial contaminants (Ref. 133). In the United States, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor has established requirements for water used for washing workers' hands. Under 29 CFR 1928.110(b), a hand-washing facility means ''a facility providing either a basin, container, or outlet with an adequate supply of potable water, soap and single-use towels;'' and potable water means ''water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the quality standards prescribed by the U.S. EPA's National Primary Drinking Water Regulations [NPDWR] (40 CFR part 141).'' The OSHA requirements in 29 CFR 1928.110 require that farms employing eleven or more employees engaged in hand-labor operations in the field for a period of more than three hours in a day provide water that satisfies the microbial maximum contaminant level (MCL) in the NPDWR, which states that any generic *E. coli*-positive repeat sample or generic *E. coli*-positive routine sample (which would include a finding of any detectable generic *E. coli* in 100 ml of water using the methods of analysis in proposed subpart N) constitutes a violation of the MCL for total coliforms. Therefore, the microbial standard for hand washing water during harvesting, packing, and holding activities that is specified in proposed § 112.44(a) would be consistent with the OSHA requirements.

We acknowledge the difficulty of associating specific indicator concentrations with specific produce related health risks. Even so, we have tentatively concluded that such difficulty does not negate the value of applying generic *E. coli* test results to the requirement to discontinue use of a water source until compliance with applicable generic *E. coli* standard is again achieved, because elevated indicator organism concentrations indicate increased levels of fecal contamination and elevated potential for the presence of human pathogens of fecal origin (Ref. 154). The uses listed in proposed § 112.44(a) are similar in that, if pathogens or fecal contamination are present, it is reasonably likely they could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the water. Therefore, testing the agricultural water used for these purposes to ensure that it is absent of generic *E. coli* would provide reasonable assurances that the water does not contain pathogens, and therefore that the water is not likely to introduce pathogens into or onto covered produce and to provide reasonable assurances that the produce will not be adulterated under section 402 of the FD&C Act. Moreover, a requirement that there be no detectable generic *E. coli* per 100 mL of agricultural water used in these activities and practices would be consistent with EPA's MCLs for microbiological contaminants in public drinking water systems (40 CFR 141.63(b)) and with our standard of quality for bottled water (21 CFR 165.110(b)(2)(B)). We request comment on the need for, and appropriateness of, this proposed requirement and any other criteria that would ensure the safety of water for these intended uses.

We tentatively conclude that we should require that if the water you use for the purposes listed in § 112.44(a) does not meet the microbial standard of no detectible generic *E. coli* per 100 ml, you must immediately discontinue use of the water and/or distribution system for those purposes. Before you use the water source and/or distribution system again for those uses, you would need to either (1) re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the required microbial standard; or (2) treat the water in accordance with the requirements of § 112.43 (proposed § 112.44(b)). This proposed requirement is parallel to the requirement in proposed § 112.42(d), which is discussed above.

Proposed § 112.44(c) would require that when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in § 112.44(c). Before you may use the water source and/or distribution system again for the uses described in § 112.44(c), you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were

effective; or treat the water in accordance with the requirements of § 112.43. We seek comment on this approach.

As discussed in section V.E.2 of this document, the WHO recommends monitoring generic *E. coli* numbers in treatment effluents as verification of wastewater treatment, and laboratory analysis of crop contamination levels with generic *E. coli* at harvest and in retail to verify pathogen mortality (die-off) (Ref. 118). However, they also noted the variability in pathogen die-off (0.5–2 log/day), dependent on temperature, sunlight intensity, crop type, time of water application, and other factors.

Some industry groups have adopted the generic *E. coli* component of the U.S. EPA recreational water standards (for beaches used frequently) for certain uses of agricultural water (Ref. 31. Ref. 44). In this regard, EPA recommends that criteria include a maximum steady state geometric mean of 126 CFU of generic *E. coli* per 100 ml and a single sample maximum allowable density of 235 CFU of generic *E. coli* per 100 ml (Ref. 136). British Columbia, Canada has announced their intention to use generic *E. coli* criteria for irrigation water used on produce consumed raw. Their irrigation criteria (less than or equal to 77 CFU per 100 ml geometric mean) are the same as and were derived from those used for primary-contact recreation (Ref. 137). Similarly, the generic *E. coli* component of EPA's recreational water standard (for beaches used frequently) serves as the basis for our proposed standard for microbial water quality for water used in direct application methods during growing (proposed § 112.44(c)).

It should be noted that EPA's recreational water standards for beaches used frequently also includes a recommendation for a maximum steady state geometric mean of 33 CFU of enterococci per 100 ml and a single sample maximum allowable density of 61 CFU of enterococci per 100 ml (Ref. 136). Similarly, the current British Columbia criteria for irrigation water used on produce consumed raw is a geometric mean of less than or equal to 200 CFU fecal coliform per 100 ml and they have announced their intention to use a geometric mean of less than or equal to 20 CFU enterococci per 100 ml (along with generic *E. coli,* as discussed above). We have tentatively concluded to not include enterococci or fecal coliform in our proposed standard at § 112.44(c) because we believe generic *E. coli* to be the superior indicator of fresh water quality and do not believe that the added cost of testing for both generic *E. coli* and enterococci is warranted. Wade et al (2003) (Ref. 155) performed a systematic review of 27 studies of water quality indicators used for the regulation of recreational waters. They compared the ability of enterococci, fecal coliform, generic *E. coli* and total coliform levels to predict for the occurrence of gastrointestinal illness. They concluded that for freshwater, generic *E. coli* was the more consistent predictor. Working under the framework of a WHO project for setting guidelines for quality of recreational waters and bathing beaches, Pruss (1998) (Ref. 156) reviewed 22 studies on uncontrolled waters (seas, lakes, and rivers) for dose-related relationships between GI illness and bacterial indicator (most commonly generic *E. coli,* enterococci, and fecal coliforms) counts. The author found the two indicator organisms which correlate best with health outcomes were enterococci for both marine and freshwater and generic *E. coli* for freshwater.

We considered proposing a drinking water standard for water used on covered produce other than sprouts during growing in a direct water application method, but tentatively conclude that such criteria would be unnecessarily restrictive as it would not sufficiently account for forces driving pathogen die-off (*e.g.,* sunlight, competing microorganisms) (see section V.E.2 of this document). We also considered proposing a second lower microbial quality criteria for water used in growing, but where the water used for irrigation is not reasonably likely to contact the edible portion of the covered produce (*e.g.,* surface irrigation of tree crops). However, we are not aware of another standard for which there is sufficient scientific support.

We acknowledge that the EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136), rather than to consumption of produce. These epidemiological studies were performed in beach areas subject to point source fecal contamination rather than non-point sources (*e.g.,* birds, agricultural and livestock runoff), which may impact agricultural water. Further, risks of adverse health outcomes resulting from full body contact in contaminated water may be different than risks associated with consuming produce irrigated with contaminated water, given the differences in the expected routes of infection and pathogen mortality rates in the different environments (bodies of water for the EPA recreational water standards; soil, plants, and produce for this proposed rule).

We also acknowledge that the proposed standard is more stringent than the WHO standard. Based upon an analysis of tolerable risk for irrigation water, WHO recommends that the minimum microbial quality for water used on root crops that are eaten raw is 1000 CFU generic *E. coli* per 100 ml (10,000 CFU generic *E. coli* per 100 ml in leaf crops) (Ref. 118. Ref. 120). According to the WHO analysis, using water of this microbial quality is dependent upon a 2 log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1 log reduction attributed to washing prior to consumption. This analysis recognizes the variable nature of die-off values, ranging from 0.5–2.0 log per day (Ref. 118). The WHO analysis considers the need for a four log reduction through dilution, die-off, or treatment between the levels of generic *E.coli* in raw sewage (well represented in sewage by fecal coliform levels) and the levels in irrigation water used on root crops that are eaten raw (3 log for leaf crops), in addition to the 3 log reduction discussed above.

We tentatively conclude that the recreational water generic *E. coli* criteria would serve to minimize risk of known or reasonably foreseeable hazards when used as a standard for agricultural water used on produce other than sprouts during growing in a direct water application method. We recognize that is somewhat more protective than the WHO standard, which we believe is appropriate given the uncertainty in die-off values. We request comment on the need for, and appropriateness of, this requirement or other criteria that would ensure the quality of agricultural water used for this purpose.

We tentatively conclude that if agricultural water you use on produce other than sprouts during growing in a direct application method does not meet the microbial water quality described in § 112.44(c), you must immediately discontinue use of that source of agricultural water and/or its distribution system and either (1) re-inspect the agricultural water system components under your control, identify conditions that are reasonably likely to introduce hazards to the system, make necessary changes based upon your observations, and retest the water to determine if your changes were effective; or (2) treat the water in accordance with the requirements of § 112.43. This proposed requirement is parallel to the requirement proposed § 112.42(d), which is discussed above.

We tentatively conclude that violation of microbial water quality standards proposed in §§ 112.44(a) and (c) in and of itself would not necessarily establish evidence of adulteration of covered produce subjected to use of the water, nor would it necessarily mean that the food was contaminated. However, use of water that is shown to violate these standards would violate the requirement at proposed § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. As described immediately above, these proposed standards are based on likelihood of fecal contamination (as indicated by the presence of generic *E. coli*), that we have tentatively concluded minimize the risk of serious adverse health consequences or death by preventing the introduction of hazards and providing reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. Agricultural water in violation of these standards indicates increased likelihood of fecal contamination of the water and, consequently, increased likelihood of produce contamination with human pathogens, beyond that which is appropriate for the intended use. Therefore, we propose to require you to immediately discontinue use of that source of agricultural water and/or its distribution system until you have either followed certain prescribed steps to mitigate the problem or treated the water.

Under the provisions of proposed § 112.44, if covered farms choose to treat irrigation water in accordance with the requirements of proposed § 112.43, any chemicals used in such treatment would require registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used. At the present time, no such registration for chemical treatment of irrigation water exists. As discussed in section IV.K. of this document, FDA is proposing to delay implementation of certain provisions, including the water quality testing requirements in proposed § 112.44, beyond the effective dates for other provisions of the rule. The proposed extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) are six years from the effective date for very small businesses, five years from the effective date for small businesses, and four years from the effective date for all other farms subject to the rule. We expect these extended compliance dates to provide adequate time for industry to address issues related to water quality testing. We seek comment on the adequacy of this timeline.

Proposed § 112.44(d) would also allow you to establish and use alternatives to the requirements established in proposed § 112.44(c) provided you satisfy the requirements of proposed § 112.12. As discussed in section V.B. of this document, under proposed § 112.12(a)(1), you may establish an alternative to the requirements, established in proposed § 112.44(c) for testing water, and taking action based on test results when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method. We acknowledge that in specific circumstances an alternative standard (*e.g.,* a standard that applies an application interval (time between application and harvest) in place of the § 112.44(c) standard, but is specific to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. Therefore, we tentatively conclude that it would be appropriate to allow for alternatives to the requirements in proposed § 112.44(c).

We are working with USDA and other stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier).

Proposed § 112.45 would establish requirements related to frequency of testing agricultural water that is subject to the requirements of § 112.44. Specifically, proposed § 112.45(a) would require that you test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every three months thereafter during the growing season, except that there would be no requirement to test water when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR Part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

Water testing frequencies recommended by various industry documents vary widely, in part because there is a lack of publicly available information pertaining to the quality of irrigation waters. Recommendations range from monthly testing to once each year, for sources with a history of compliance with commodity specific recommendations (Ref. 31. Ref. 44). Even for sources considered reliable (*e.g.,* well water), a one year period between testing does not minimize the risk of known or reasonably foreseeable hazards because microbiological water quality, even when sourced from ground water sources, is too variable for this frequency of testing to be protective (*e.g.,* effects of flooding, runoff) (Ref. 29). Alternatively, we tentatively conclude testing more frequently (less than every 3 months) would not significantly improve the accuracy of your assessment of ground water quality and would therefore be unnecessary. We also considered proposing testing frequencies established as a function of commodity, irrigation method (*e.g.,* furrow, seep, subsurface dripfoliar), and timing of application (days prior to harvest), and concluded that the most effective approach is to test on a frequency related to the reliability of the agricultural water sources. We tentatively conclude that requiring testing as a function of time before harvest would be impractical for many farms as we have observed single sources (*e.g.,* a well) providing water for multiple crops in different phases of production. We request comment on whether we should allow for adjustment of ground water testing frequencies dependent upon historical test results. For example, we are considering requiring testing ground water sources every three months for one year and yearly after that if the ground water consistently met the standard. We also request public comments on our proposed approach to frequency of testing, each of the options described here, and any other alternative testing frequencies that can be supported by water quality data.

Proposed § 112.45(a)(1) provides an exception to testing required in § 112.45(a) when the water is sourced from a Public Water System or State authority approved to administer the SDWA public water supply program, and you have results of the water testing or certificates of compliance that demonstrate that the water meets the requirements of that program. These systems operate so that the water they deliver meets the microbial requirement in 112.44(a). In the U.S., Public Water Systems are required under U.S. EPA National Primary Drinking Water Regulations (NPDWR) in 40 CFR 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination. Under the sampling, testing and reporting requirements of 40 CFR 141, we tentatively conclude that additional actions by the grower to assure its safety are unwarranted. Similarly, proposed § 112.45(a)(2) provides for an exception to testing when the water is furnished from a public water supply that furnishes water that meets the standards of § 112.44(a), and you have results of the water testing or certificates of compliance that demonstrate that the water meets that standard. The standard in § 112.44(a) is derived from the EPA drinking water standard, and this provision is included to accommodate foreign public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of proposed § 112.44(a). Where public water that meets or is comparable to (in other countries) EPA's drinking water standards is used in produce operations, we are not aware of anything suggesting a need for additional testing at its delivery point to the farm. We seek comments on this issue, including any practice(s) that could materially change the quality of public or municipal water between treatment and delivery to the farm, including changes in water quality during water distribution and holding. Finally, § 112.45(a)(3) exempts from testing water that you treat in accordance with proposed § 112.43, which is discussed above.

Proposed § 112.45(b)(1) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44, and if the untreated surface water is from any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake), then you must test the water at least every 7 days during the growing season. Proposed § 112.45(b)(2) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44, and if the untreated surface water is from any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm man-made water reservoir), then you must test the water at least once each month during the growing season.

Surface water is subject to a great number of environmental factors that may alter its microbial water quality as discussed in the QAR and, when untreated, presents a significant source of pathogen contamination of produce. We tentatively conclude that the most important among these is runoff, because it has the potential to increase the number of pathogens in the water column if its origins include human, livestock or wildlife feces and because it has the potential to increase the amount of suspended sediments, which are likely to harbor pathogens (Ref. 157. Ref. 154). In proposing these testing frequencies, we tentatively divided untreated surface water into two categories based upon their potential to be impacted by runoff and the degree to which you reasonably could be expected to exercise protection and control over them. Flowing surface waters (*e.g.,* river, stream, or creek) or sources that are not protected against runoff (*e.g.,* natural ponds, lakes) must be tested at a relatively higher frequently than surface waters for which you have direct control and which you can manage in a way so to minimize the effect of runoff and other sources of contamination (*e.g.,* on-farm reservoir or pond). Contamination events that can lead to surface water contamination can have profound effects on the quality of the water, but those effects can be fleeting, especially those involving runoff from rainfall (several days to several weeks). After the contamination event passes, water quality generally returns to background levels (Ref. 158). If sampling is less frequent than weekly from surface water sources subject to these kinds of contamination events, there is a good chance that some contamination events will go undetected. On the other hand, for surface water sources that are not subject to significant runoff, the water quality tends to remain stable, and the purpose of sampling is primarily to accurately characterize the background level. Monthly sampling provides 12 samples per year that give a good representation of the quality of water through the seasons. The sampling and testing frequencies proposed in § 112.45(b) are the minimum that we tentatively conclude provide sufficient information concerning your source surface water quality for you to use in determining method of application and its timing for which the water is safe and of adequate sanitary quality. We encourage additional sampling if you have reason to believe that its quality may have changed from the previous test. We welcome comments on the need for, and appropriateness of, our proposed testing frequencies, including any alternative approaches and examples where testing should be more or less frequent based upon your experience or observation.

The monitoring frequencies proposed in this rule are practical intervals that we tentatively conclude are reflective of the varying potential for changes in water quality between ground aquifers and surface watersheds. In proposing the monitoring frequencies for untreated surface waters, we considered factors that are most likely to impact water quality. Precipitation and its effects (*e.g.,* discharge and flow rate) along with temperature are common factors reported to affect the microbial quality of watersheds with agricultural land inputs (Ref. 159. Ref. 158). Precipitation levels have also been successfully used to manage openings and closings of molluscan shellfish harvest areas. These harvest areas are well characterized in terms of changes in the microbial water quality due to non-point source runoff as a consequence of rainfall. However, we have not proposed surface water testing frequency based upon precipitation because such an approach would require full characterization of its effects (Ref. 143) on the quality of surface water sources that are not likely to be generally useful across farms, States, or regions. Our approach to testing untreated surface water is to propose practical intervals of testing both because they are likely to capture transient events that may degrade quality and because they are useful regardless of geographic location. We welcome comments on this approach, including any alternate approaches, specifically if you believe that surface waters can be thoroughly characterized such that they require less frequent testing than proposed in § 112.45.

e. Requirements for Water Used in Harvesting, Packing, and Holding Activities

Proposed § 112.46 would establish the measures you must take for water that you use during harvest, packing, and

holding activities for covered produce. Specifically, proposed § 112.46(a) would require that you manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce). The proposed language allows sufficient flexibility for you to establish measures that are best suited to your needs based on practice and experience. For example, you may establish a water-change schedule for water used in an apple flume based upon the rate of product flow, organic load, or other variables you determine best correlate with safety and sanitary quality of the flume water. Many commonly used wash water antimicrobials have decreased efficacy when organic matter is present in the water. For example, organic matter builds up in agricultural water flume systems from dirt and debris on the surface of fresh produce that are placed into the flume systems. Once the soluble and/or insoluble organic load builds up to sufficiently high levels, the addition of wash water antimicrobials becomes ineffective and inefficient. Changing the flume water on a regular basis, based on that system's unique operating conditions, can assure that wash water disinfection treatments are consistently effective (Ref. 149. Ref. 150). We point out that while water disinfection is one means to manage water quality, we are not specifically proposing to require disinfection treatment of re-circulated or single use water that is used in harvesting, packing, or holding activities. We are proposing that re-circulated or single pass water must be safe and of adequate sanitary quality for its intended use (§ 112.41) and that it contain no detectable *E. coli* (§ 112.44(a)). Further, if you have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, proposed provisions in § 112.43 for water treatment can be applied. However, we are not proposing treatment of water as the only option. Other options for farms include making changes to the system and retesting the water successfully (§ 112.42(d)) and using the same water source for other uses for which it does qualify. For example, using water that does not meet the zero *E. coli* standard but does meet the 235 CFU per 100 ml standard for direct application method irrigation of produce other than sprouts; or for water that does not meet the 235 CFU per 100 ml standard, applying the water for irrigation in a different manner that is not a direct application method (§ 112.44). These provisions offer flexibility for farms to choose among different options to ensure that the water is safe and adequate for the purpose for which it is intended. Should farms choose to disinfect water as a measure to control waterborne hazards during handling during and after harvest, we tentatively conclude that an effective disinfection program would render such water safe and of adequate sanitary quality. However, we request public comment on the appropriateness of this tentative conclusion and on whether a provision specifically directed to disinfection of water used during and after harvest is needed. We also seek public input regarding practices or conditions when disinfection of re-circulated or single use water would be unnecessary, inappropriate, or impractical.

Proposed § 112.46(b) would require that you visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for build-up of organic material (such as soil and plant debris). Organic matter such as soil and plant debris has to the potential to adversely affect the quality of water; it may be a source of bacteria (including pathogens), support the growth of bacteria, and reduce the effectiveness of antimicrobial compounds (*e.g.,* chlorine compounds) (Ref. 150). Such monitoring allows you to recognize conditions that require action, such as a water change in a dump tank.

Proposed § 112.46(c) would require that you maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce. Water temperature can influence processes leading to infiltration of microorganisms into many types of produce. As discussed in the QAR, infiltration of water containing pathogens into produce has been demonstrated in apples (Ref. 160), oranges (Ref. 161), tomatoes (Ref. 138. Ref. 139), and mangoes (Ref. 38) and was suggested to play a role in a 1999 *Salmonella* outbreak associated with mangos (Ref. 162). A recent study demonstrated that additional factors, such as tomato variety and the time delay between tomato stem removal and water immersion have a significant impact on the frequency and population of internalized *Salmonella* in tomatoes. (Ref 140). However, this study also demonstrated that *Salmonella* internalization of tomatoes via their stem scar can occur even under a zero temperature differential, and temperature differentials up to 10 °F have no effect on the internalization frequency and have limited impact on *Salmonella* cell populations internalized in tomatoes.

We considered proposing a single standard on temperature differential between water and product core temperature (*e.g.,* water must be at least 10 degrees F warmer than core) but tentatively conclude that there is insufficient scientific evidence supporting such a standard across all covered produce. However, we recognize the North American Tomato Trade Work Group and California Tomato Commission have recommended such a standard (Ref. 44). We seek public comment on the need for, and appropriateness of, the proposed provisions, including any alternative approaches that you found to be effective through experience or observation.

f. Records Requirements

Proposed § 112.50 would establish requirements about the records that you would need to establish and keep under this proposed subpart E. Specifically, proposed § 112.50(a) would require that you establish and keep records required under this proposed subpart E in accordance with the requirements of proposed subpart O. Proposed § 112.50(b) would require that you establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of proposed § 112.42(a);

(2) Documentation of the results of any analytical tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1);

(4) Documentation of the results of water treatment monitoring under § 112.43(c)(2);

(5) Documentation of the results of water testing you perform to satisfy the requirements of § 112.44;

(6) Scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d); and

(7) Annual documentation of the results or certificates of compliance from a public water system under 112.45(a)(1) or (2), if applicable.

Proposed § 112.50(b)(1) would require that you establish and keep records of agricultural water system inspection findings in order for FDA to verify compliance with the proposed requirement to inspect the agricultural water system. The records would also allow you to more effectively manage your agricultural water, to identify trends and changes in your agricultural water system over time, and to help identify potential sources of contamination of the water system and covered produce. In addition, these records may aid you in determining the most appropriate frequencies for maintenance of well and surface water sources, distribution and holding systems.

Proposed § 112.50(b)(2) would require that you establish and keep records of any analytical test results from any tests you may have conducted to determine if water meets the quality requirements proposed in § 112.41. We have tentatively concluded that these records are necessary because otherwise FDA would have no way to determine whether you were making appropriate decisions about whether your water is safe and of adequate sanitary quality for its intended use. When such tests are conducted, results of those tests are also fundamental in making informed decisions concerning your use of water.

We are proposing under § 112.50(b)(3) and (4) that you must establish and keep scientific information or data documenting the effectiveness of the treatment method that you use and records demonstrating that you deliver the treatment consistently to ensure the water is safe and of adequate sanitary quality. These records may include information provided by the antimicrobial product supplier, product labels with instructions for use, product material safety data sheets (MSDS), batch test results demonstrating correct active ingredient concentration, mixing proportions, and schedules or application rates you have developed to ensure water is treated effectively. They may also include results of testing you perform to confirm your treatment methods are being followed, such as records of active ingredient concentration, pH, temperature, flow rate, immersion time, or water changes, if they significantly impact the effectiveness of the treatment. Monitoring frequency may be affected by product flow, organic load on incoming product, temperature, UV exposure, and consumption rates or breakdown rate (expected and observed) for the active antimicrobial compound, among other factors. These records are necessary so that FDA can verify your compliance with those requirements. They will also allow you to ensure your own compliance with the requirements for water treatment in proposed § 112.43.

We are proposing in § 112.50(b)(5) that you must establish and keep records of the results of water testing you perform to satisfy the requirements of § 112.44. For example, records for water tests you perform to ensure input water used in sprout production meets the requirements in § 112.44(a) would include, at a minimum, the test date, specific water source (*e.g.,* municipal water or well number 3), method name (*e.g.,* multiple tube fermentation, membrane filter method, presence-absence test, and commercial product name, if applicable) and the test result (*e.g.,* not detected, generic *E. coli* MPN or CFU, as applicable). Records you maintain to demonstrate the microbial water quality meets the requirements of § 112.44(c) for foliar application of spinach would include, at a minimum, the test date, specific water source (*e.g.,* ranch X, well 3 or canal collection point 2), method name (*e.g.,* multiple tube fermentation, membrane filter method, and commercial product name, if applicable) and the test result (*e.g., E. coli* MPN or CFU, as applicable). We tentatively conclude that documentation of the results of water testing are necessary to demonstrate that the water you use meets the requirements of § 112.44 and to provide a history of the microbial quality of your water system, which will be useful in spotting problems before they occur, minimizing the potential for water to be a source of contamination to covered produce. These records are necessary so that FDA can verify your compliance with those requirements and so that you can ensure your own compliance with the requirements for water testing and responding to test results in proposed § 112.44. In proposed § 112.50(b)(6), we would require you to establish and keep that scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d). Such documentation will enable us to verify, and you to ensure, that the alternative standard you use provides the same level of public health protection as the standard in proposed § 112.44(c) and does not increase the likelihood that the covered produce will be adulterated, in accordance with proposed § 112.12.

We are proposing in § 112.50(b)(7) that if you use water from a public water system, you must establish and keep annual documentation (*e.g.,* certificate of compliance, water quality testing results) demonstrating that system supplies water meeting the microbial requirements of § 112.45(a)(1) or (2), if applicable. We tentatively conclude that maintaining such annual documentation is necessary for FDA to verify that the water you use is not subject to the requirements for testing under proposed § 112.45 and to ensure that it meets the microbial requirements of proposed 112.44, and for you to demonstrate that those requirements have been met. We seek comment on the appropriateness of the proposed record-keeping requirements.

F. Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

Proposed subpart F establishes standards directed to treated and untreated biological soil amendments of animal origin and human waste. These standards include requirements applicable for determining the status of a biological soil amendment of animal origin; procedures for handling, conveying, and storing biological soil amendments of animal origin; provisions regarding the use of human waste in growing covered produce; acceptable treatment processes for biological soil amendments of animal origin applied in the growing of covered produce; microbial standards applicable to treatment processes; application requirements and minimum application intervals; requirements specific to agricultural teas; and records requirements. The proposed requirements in subpart F derive from current recommendations in our GAPs guidance (Ref. 10), commodity-specific guidances (Ref. 31) (Refs. LGMA), State regulations (Ref. 90. Ref. 163. Ref. 164), other Federal Regulations (40 CFR 503, 7 CFR 205), and international guidelines (Ref. 100. Ref. 51).

1. Comments Relevant to Proposed Requirements

We received several comments in response to the 2010 FR notice that addressed issues relevant to biological

soil amendments of animal origin and human waste.

a. Definitions

One comment stated that manure and compost are two different things, and the two words should not be used interchangeably as it causes confusion. We agree. As discussed in the QAR, and noted in the Produce Safety Project Issue Brief on Composting of Animal Manures there are documented differences in the populations and level of human pathogens in raw manure and animal feces and in properly composted manure (Ref. 27). We are proposing definitions that make the distinction clear. We are proposing to use the phrase ''untreated biological soil amendments of animal origin'' as a category that includes raw manure (see proposed § 112.3(c) and section V.A.2.b.iii of this document regarding ''biological soil amendment of animal origin,'' and proposed § 112.51(a) and section V.F.2.a of this document regarding ''untreated'' biological soil amendments of animal origin). We use the term ''treated biological soil amendments of animal origin'' to include treatments that meet the requirements of the standards presented in this subpart (see proposed § 112.51(a) and section V.F.2.a of this document). To further alleviate confusion, we use the term ''compost'' as a verb, to mean the act of composting, and do not use it as a noun to describe a soil amendment that was treated by a composting method. Instead, we use the term ''humus'' in its common agricultural meaning (see proposed § 112.3(c) and section V.A.2.b.iii of this document).

b. Consideration of Other Regulations and Guidances

Comments from growers whose operations are certified for organic produce requested us to ensure that our regulations do not interfere with existing organic certification systems or organic production practices. Another comment stated that the *California code of regulations for composting yards* (Cal. Code Regs. title. 14, ch. 3.1) would be an acceptable starting point in developing our regulations.

We consider that organic production practices and food safety are not cross-competing goals. In developing the provisions proposed in this rule, we consulted with technical experts and representatives from other Federal Agencies, including the Environmental Protection Agency, the Department of Agriculture (including both the National Organic Program and the Natural Resources Conservation Service), and the Department of the Interior (Fish & Wildlife Service) (Ref. 115). As discussed in section III.A.8. of this document, we tentatively conclude that compliance with the provisions of this proposed rule would not preclude compliance with the requirements for organic certification in 7 CFR part 205, and we seek comment on this tentative conclusion. Use of organic practices alone is not sufficient to ensure food safety. The use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil. On this particular issue, and as discussed in sections II.E.4 and V.B of this document, we are working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. We also note that we considered several regulations, recommendations, and guidelines that address soil amendments, including those from State, federal, and international agencies, industry, and trade associations (including the California code of regulations for composting yards). In addition, we consulted with experts from multiple organizations and academia for scientific and technical input on the issues addressed in these provisions. The provisions proposed take into account information and input gathered through these consultations.

c. Treatments, Processes, and Practices

One comment suggested that many growers are accepting food waste compost, which has no manure in it but can often have a readily detectable level of *Salmonella,* and stated that ''green waste'' (or similar) does not necessarily equate to zero risk. Comments stated that if raw manure is used, there should be a science- and risk-based standard for determining the application-to-harvest waiting interval and that maximizing the time interval between soil amendment application and harvest is only logical if using fresh manure. Similarly, one comment stated that raw manure can be applied to soil if it is plowed and then given sufficient time before planting.

Our review of various composting methods suggests that, regardless of the source, if the process is properly conducted (including proper turning of feedstock) the expected pathogen load and subsequent likelihood of produce contamination can be minimized. We agree that certain sources, including plant material (Ref. 165) and animal sources (Ref. 166), have differing likelihood of containing human pathogens or higher population levels of human pathogens. To address this concern, we propose separate, but related, provisions. First, we do not propose treatment or timing restrictions for biological soil amendments that do not contain any animal waste product or human waste (such as would be the case with yard waste, purely vegetative matter, or shrub trimmings, or agricultural teas made from such materials). Such biological soil amendments would not be subject to the requirements in proposed subpart F because they would not fit the definition of ''biological soil amendments of animal origin'' and they do not contain human waste. Further, in § 112.51(b)(4) we propose that a biological soil amendment of animal origin contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness, you must regard it as if it were an untreated biological soil amendment of animal origin for application and treatment purposes if you still wish to utilize it. In addition, we treat ''table waste'' as ''animal waste'' for the purposes of the definition of biological soil amendments of animal origin. As discussed in the QAR, post-consumer waste, or table waste (such as plate scrapings), has a greater likelihood of being contaminated, or contaminated at higher populations, with human pathogens due to its unknown content (*e.g.,* animal products, vegetable products, etc.) and its greater likelihood of containing human fluids or waste (*e.g.,* spittle, vomitus, etc) (Ref. 167).

Proposed § 112.56(a)(1)(i) would require that if you apply a biological soil amendment of animal origin that is untreated (such as raw manure), where covered produce is reasonably likely to contact the soil after application, the material must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application and the minimum application interval is nine (9) months. In section V.F.2.f. of this document we discuss the reasons for this proposed requirement in detail. Proposed § 112.56(b) would allow you to establish and use an alternative application interval under certain conditions (discussed further in section V.B. of this document). In situations where the covered produce will not contact the soil after application, proposed § 112.56(a)(1)(ii) would require that the biological soil

amendment of animal origin be applied in a manner that does not contact the produce at or after application, but would not require an application interval. Also, as discussed in section II.E.4. of this document, FDA is collaborating with partners on research that may provide scientific support for specific alternatives to this proposed application interval.

One comment stated that compost made with animal manure must meet temperature, mixing, and time requirements to ensure its safety, whereas another comment stated that biologically active soil suppresses pathogens and that *E. coli* pathogens decline more rapidly in soils with a large diversity of microorganisms rather than in sterile soils. One comment recommended that we require compost operations to have standard operating procedures, a quality assurance plan, compost testing within specified timeframes of sale, and a Hazard Analysis Critical Control Point (HACCP) program. According to this commenter, several growers are requesting testing prior to purchase, and are refusing compost that has not been recently tested.

Based on our review of the literature and as discussed in our QAR, we determined that improper composting will not have the desired pathogen reduction effect, and may enhance the survival of pathogenic organisms (Ref. 168). Therefore, we propose specific time and temperature controls for composting procedures in proposed § 112.54(c), and further recognize the need for composters to consider other factors that will impact the successful treatment of their particular composting situation (*e.g.,* feedstock, C:N ratios, pH). We consider that the potential effects of soil ecological diversity on pathogen populations are regionally specific, and may be highly effective under some circumstances, while potentially inert under other circumstances. We recognize the need for consistent treatment by suppliers of treated biological soil amendments of animal origin, and for assurance by those that use such amendments that the material has been produced under adequate conditions, to avoid it being a source of contamination. We have tentatively concluded that the most reliable and least burdensome proposal regarding the use of purchased treated biological soil amendments of animal origin is to require growers to obtain certain documentation (such as a Certificate of Conformance) from the treating operation that validated treatment methods were utilized, the treatment process is periodically verified through testing, and good handling practices were followed. This is proposed in subpart 112.60(b)(2) and we request comment on this proposed requirement, including periodic verification through testing.

d. Testing for Pathogens

Several comments suggested that variable minimum application-to-harvest waiting intervals should be applied using science-based knowledge about pathogen levels in and transfer from compost, and that if a compost tests pathogen-free, there should be no time limit between application, planting, and harvest. Another comment stated that pathogen testing has significant limitations, and that it would be more important to evaluate a treatment process to ensure that it is effective in inactivating pathogens.

We considered testing of individual lots of biological soil amendments of animal origin as a means to determine if they were suitable for application to a fresh produce growing area and tentatively conclude that such testing is not a reliable means of determining the safety or expected likelihood of contaminating produce by use of biological soil amendments of animal origin. We have multiple concerns that led us to this conclusion. First, we were unable to determine standardized testing methods, such as sample collection methods, sample collection times, or location of sample collection, which would yield repeatable and reliable results under different circumstances. Second, we were unable to determine the frequency and sample size that would reliably indicate the microbiological safety of a given manure lot. Third, we recognize that there are numerous pathogens which may be present in biological soil amendments of animal origin and that pathogen testing would be necessary for all such potential contaminants, which would be a significant economic burden. Therefore, we tentatively conclude that an approach that is the most reasonable and the most protective of public health would involve the use of treatments that have been validated to meet certain specified microbial standards as proposed in this subpart.

e. Research Needs

Some comments suggested that there is a need for research to identify means other than through heat to inactivate pathogens, and that such alternative approaches may be more practical for farmers. Comments opined on the use of chemical inactivation, and noted that the effectiveness of use of volatile acids or ammonia in the inactivation of pathogens is not fully established but that further research may help refine time and temperature parameters for chemical inactivation.

We agree that further research and innovation may lead to alternatives to heat treatments. Proposed § 112.54 addresses the use of physical processes, chemical processes, or combinations of physical and chemical processes, in addition to composting, that may be used as treatments for biological soil amendments of animal origin, provided that they meet the applicable requirements of § 112.55 and the treated biological soil amendment of animal origin is applied in accordance with the applicable requirements in § 112.56. We consider heat treatments to be physical processes within the meaning of that term in § 112.54, and we have purposefully chosen the broader term ''physical processes'' to allow for possibilities other than heat treatment. Thus, these proposed requirements would allow for the use of alternatives to heat treatment, and are intended to be flexible to foster innovation and development of new means of treating biological soil amendments of animal origin to ensure produce safety.

2. Proposed Requirements

As proposed in § 112.3, ''soil amendment'' would be defined to mean any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. Additionally, ''biological soil amendment'' would be defined in § 112.3 to mean any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination. Finally, proposed § 112.3 would define ''biological soil amendment of animal origin'' to mean a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination, and would specify that the term does not include any form of human waste. See section V.A.2.b.iii. of this document. Proposed subpart F is focused on biological soil amendments of animal origin, which include animal

manures and other materials of animal origin that you intentionally add to a growing area, and on human waste. Standards directed to animal feces deposited by domestic or wild animals that are not a part of your planned growing activities (*e.g.,* by working animals, by animals that graze or encroach into your growing areas) are proposed to be included in subpart I, as discussed in section V.I. of this document.

As discussed in the QAR, animal waste is likely to contain bacterial pathogens (*e.g., Campylobacter, Salmonella* spp., enterohemorrhagic *E. coli*) and various other pathogens such as parasites (*e.g., Cryptosporidium parvum, helminthes*), which may infect humans. The type of pathogen that may be present, and the extent to which it may be present, is dependent on the source of the manure (*e.g., E. coli* is more common from ruminants such as cattle, whereas *Salmonella* is more common from fowl such as chickens) and the rearing practices of the source animals (*e.g.,* animals from densely populated farms or farms with a high population of immature animals have an increased likelihood of harboring various pathogens) (Ref. 169). Enteric (or gastroinstestinal) pathogens are not generally considered to be environmental, and are more commonly expected to be derived (and in higher populations) from a human or animal source (*e.g.,* through feces, mortalities, blood, spittle, etc.) (Ref. 170). Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that can reasonably be expected to lead to severe adverse health consequences or death (Ref. 94). We have tentatively concluded that the likelihood of contaminating produce by use of biological soil amendments that do not contain animal waste or human waste (*e.g.,* yard trimmings, pre-consumer vegetative waste) carrying human pathogens is low. Similarly, we are unaware of a situation in which chemical and physical soil amendments, such as elemental fertilizers (*e.g.,* potash, aqueous nitrates), soil stabilizers (*e.g.,* sand or crushed rock) or others typically made of mined or synthetic materials, have served as sources of microbial contamination and, therefore, neither chemical nor physical soil amendments are a focus of provisions of this rule. Therefore, in this proposed subpart F, we are proposing to focus on biological soil amendments of animal origin and human waste, which present a reasonable likelihood of harboring human enteric pathogens. Unless otherwise specifically noted, chemical soil amendments, physical soil amendments, and biological soil amendments that are not of animal origin (other than those that contain human waste, which are covered by proposed § 112.53) are not covered by this rule. We encourage comment on our tentative decision not to provide requirements for the use of these kinds of soil amendments in this proposed rule.

a. Requirements for Determining Status

Proposed § 112.51 would establish requirements for determining the status of a biological soil amendment of animal origin for use in covered activities. Proposed § 112.51(a) would categorize a biological soil amendment of animal origin as treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the requirements of 112.44(a). Section 112.51(b) would categorize a biological soil amendment of animal origin as untreated if: (1) It has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of 112.44(a); (2) it has become contaminated after treatment; (3) it has been recombined with an untreated biological soil amendment of animal origin; (4) it is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or (5) it is an agricultural tea that contains an agricultural tea additive.

Proposed § 112.51(a) would provide a simple method of referring to biological soil amendments of animal origin as treated if they have received one of the treatment processes described in proposed § 112.54. We discuss those treatment process options in detail in section V.F.2.d of this document. Agricultural teas are mentioned separately for two reasons. First, treatments are typically applied to the biological materials used to make agricultural teas rather than to the teas themselves and our explicit mention of this fact is intended to aid in clarity. Second, we specify that the water used to make a treated agricultural tea must meet the standard in proposed § 112.44(a) to prevent the introduction of pathogens into treated agricultural teas, which can be applied with fewer application restrictions than untreated agricultural teas in accordance with proposed § 112.56. As discussed in section V.E.2.d of this document, the conditions under which agricultural tea is produced (moist and nutrient-rich) support the multiplication of pathogens, if present (Ref. 142). Even a low number of pathogens introduced into or onto covered produce through contaminated water could rapidly increase to levels that could present risk of serious adverse health consequences or death to those who consume the covered produce for which the tea was used (Ref. 142).

Proposed § 112.51(b) addresses the situations in which a biological soil amendment of animal origin should be regarded as untreated because they present a greater likelihood of contamination to covered produce than a treated biological soil amendment of animal origin. A treated biological soil amendment of animal origin can be expected to have a high content of available nutrients and minerals which can support rapid and prolific microbial population growth if sufficient moisture is available, possibly with limited competitive native microflora (Ref. 171) (depending on the specific treatment, treatment parameters, and handling used, (*e.g.,* heat treated poultry manure pellets would be expected to have limited microorganism content including competitive native microflora, and composted manure would be expected to have substantial competitive native microflora)) (Ref. 171. Ref. 172). Accordingly, pathogens could grow prolifically in a treated biological soil amendment of animal origin if it were to become contaminated through contact or partial mixing with an untreated biological soil amendment of animal origin, or other potential contaminant source, and if sufficient moisture were available (Ref. 171). Prolific microbial growth could also occur through premature termination of treatment, which could leave surviving microorganisms and a higher moisture content than after composting is completed. In addition, if a biological soil amendment of animal origin contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness, we tentatively conclude that the increased likelihood of pathogen presence in such materials results in a need to apply the most stringent controls to their use in the growing of

covered produce. Prolific growth of a human pathogen in a nutrient-rich, possibly competition poor, biological soil amendment of animal origin could lead to the amendment acting as an inoculum that spreads microorganisms on any field or covered produce growing area to which the amendment may be applied, leading to a potential significant likelihood of produce contamination. To avoid such inoculation, we propose to require you to regard any biological soil amendment of animal origin that is partially or incompletely treated as an untreated biological soil amendment of animal origin. Finally, we tentatively conclude that agricultural teas that contain agricultural tea additives should be regarded as untreated biological soil amendments in light of their content and the likelihood that they contain human pathogens.

As discussed in section V.F.2.f. of this document, we tentatively conclude that the treatment process (including composting processes) can reduce the populations of pathogens significantly. However, it has been recently reported that while pathogens that are present in agricultural teas made from properly composted humus are reduced to undetectable levels within 8.5 days, such agricultural teas with added nutrient supplements (*i.e.,* agricultural tea additives) allow low populations of remaining *E. coli* O157:H7, *Salmonella,* and fecal coliforms to grow and multiply (Ref. 142). For this reason, we propose to impose the same application restrictions on agricultural teas that have been prepared with nutrient additives as those that we propose for the use of untreated biological soil amendments of animal origin, such as raw manure (proposed § 112.56(a)(1)(i)), and seek comment on this proposal. See section V.F.2.f. of this document for further discussion of the reasons for these restrictions.

b. Requirements for Handling, Conveying, and Storing

Proposed § 112.52 would establish requirements for handling, conveying and storing soil amendments of animal origin. Specifically, we propose in § 112.52(a) that you handle, convey, and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems. As discussed immediately above, prolific growth of a human pathogen in a potentially competition-poor, nutrient-rich, biological soil amendment of animal origin could lead to the amendment acting as an inoculum that spreads microorganisms on any field or covered produce growing area to which the amendment may be applied, as well as to food-contact surfaces, areas used for covered activities, water sources, and water distribution systems. To fulfill the proposed requirement in § 112.52(a), we would expect you to take specific measures to ensure that untreated biological soil amendments of animal origin do not contaminate covered produce directly or indirectly through contact with food contact surfaces, areas in which covered activities are conducted, water sources, or distribution systems. Such measures may include, for example, separation of treated and untreated manure (or other biological soil amendments of animal origin) and preventing any leachate originating from untreated biological soil amendments of animal origin from becoming a source of contamination for source water or water distribution systems (Ref. 173).

As discussed in the QAR, any untreated biological soil amendment of animal origin that contaminates a food contact surface could be a source of further cross-contamination to covered produce. Moreover, a biological soil amendment of animal origin that has been treated by a composting process may still have a residual population of pathogens, since composting is not a complete kill step (Ref. 174); therefore, such biological soil amendments require a multiple hurdle approach to minimize the likelihood of introducing pathogens to a field on which they are applied. If composted material contaminates a food contact surface, the combined presence of available nutrients plus any pathogens that may have survived the composting process present a potential source of contamination for any covered produce that comes in contact with the contaminated food contact surface. Further, a fully heat-treated biological soil amendment of animal origin, while reasonably likely to be free of pathogens, may act as a source of nutrients for pathogens that might contaminate the food contact surface, thereby allowing them to multiply and pose a likelihood of contaminating any produce coming in contact with the food contact surface.

As proposed, § 112.52(b) requires that you handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the likelihood of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin. This proposed requirement is necessary because a biological soil amendment of animal origin previously treated to reduce pathogens can become re-contaminated by pathogens if not properly handled and stored (Ref. 175). For example, if you fully compost manure produced by your cows with the intent of using it to amend a field you use to grow covered produce, proposed § 112.52(b) would require that you handle, convey, and store the fully composted manure in a manner and location to prevent its contamination by raw manure, or by manure in the composting process. This requirement is critical because bacterial pathogens, such as *E. coli* O157:H7 or *Salmonella* spp., if allowed to re-contaminate finished compost, may grow and spread to populations that present a significant likelihood of contaminating any environment in which the soil amendment is used (Ref. 171). An example of cross-contamination may include turning a pile of manure that is in the process of composting with a front-end loader, and then proceeding to handle fully composted humus from a mature pile with the same equipment. To avoid such cross-contamination, you could clean the front-end loader between manipulating an incomplete pile and manipulating a mature pile; move ''downstream,'' beginning with sanitary equipment and manipulating the most mature piles first, then proceeding to less mature piles; or designate certain equipment to only be used on piles of a certain maturity; or adopt other strategies that meet the same goals.

Proposed § 112.52(c) would require you to handle, convey, and store any biological soil amendment of animal origin that has become contaminated (for example, by an untreated or in-process biological soil amendment of animal origin) as if it was untreated. In other words, a treated biological soil amendment of animal origin that has become contaminated would need to be applied in accordance with the application and interval restrictions of proposed § 112.56(a)(1) for untreated biological soil amendments of animal origin, or it would need to be treated in compliance with one of the options in proposed § 112.54 and then applied in accordance with the applicable requirements in § 112.56 for the treatment used. For example, if a treated or in-process biological soil amendment of animal origin becomes unintentionally contaminated (*e.g.,* from runoff from an untreated biological soil amendment of animal origin), you would either need to treat that material in accordance with an option in proposed § 112.54 and then apply it in

accordance with the applicable requirements in § 112.56 for the treatment used, or you would have to follow the application requirements for untreated biological soil amendments of animal origin in proposed § 112.56(a)(1) for the contaminated material.

c. Prohibition Regarding Use of Human Waste

Proposed § 112.53 would prohibit the use of human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR Part 503, subpart D, or equivalent regulatory requirements. Human waste has a high probability of containing multiple diverse human pathogens, including bacteria, parasites and viruses, at potentially very large populations, thus presenting a significant likelihood of harboring and spreading these various microbiological hazards (Ref. 92). We recognize that an application of untreated human waste could occur outside of your control (for example, as a run-off event from adjacent land not under your control), or may have occurred as a previous use of land before you took possession. If you know or have reason to believe such an event has occurred, we would expect you to take measures reasonably necessary to minimize the risk of serious adverse health consequences or death based on your specific circumstances. Such measures may include crop diversion, reconditioning or destruction, and/or land remediation, or other comparable methods.

Under 40 CFR part 503 subpart D (§ 503.30, 31, 32 and 33), the U.S. EPA requires that the application of sewage sludge biosolids to fields in which food or feed crops are grown adhere to certain pathogen reduction requirements, and use certain vector attraction reduction options. Depending on which options are implemented, there are different ranges of wait periods between application of the soil amendment, and the harvest of the crop grown. For example, if an untreated human waste (*i.e.,* equivalent to domestic septage: ''Liquid or solid material removed from a septic tank, cesspool, portable toilet'') (40 CFR 503.9(f)), is applied to a field used to produce a food crop, then ''Food crops with harvested parts that touch the sewage sludge/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of sewage sludge'' (40 CFR 503.32(c)(1), cross-referencing § (b)(5) of the same section). We agree these standards are appropriate for protecting public health and, therefore, we are not proposing to implement further restrictions. Our proposed definition of agricultural teas, discussed in section V.A.2.b.iii. of this document, would provide that agricultural teas are not made from any form of human waste because doing so would not be permissible under 40 CFR part 503 subpart B.

d. Acceptable Treatment Processes

Although there is great variability in available data on pathogen survival in animal manure depending on the type and source of manure in question, the location and environment under which the manure is stored, and numerous other factors (Ref. 176. Ref. 177. Ref. 178) there are data to suggest it is reasonable to expect that, given the proper conditions, pathogens in certain animal manures may survive for months (Ref. 179), years (Ref. 180), or even indefinitely (Ref. 174). Because the use of soil amendments that contain materials of animal origin poses a significant likelihood of contaminating the growing environment and covered produce with human pathogens, we have tentatively concluded that such materials used as a soil amendment require some level of treatment, or other risk-reducing steps (such as application restrictions), for use in the growing of covered produce. Proposed § 112.54(a)–(c) would establish acceptable treatment processes for a biological soil amendment of animal origin when applied in the growing of covered produce, along with associated microbial standards against which they must be validated in proposed § 112.55. A validated process, when properly implemented and monitored, would be expected to meet the listed microbial standards and thereby reduce the likelihood of hazards associated with biological soil amendments of animal origin from contaminating covered produce. The microbial standards in proposed § 112.55 are not meant as lot-by-lot microbial testing requirements. Instead, the person applying the treatment process would need to monitor the physical parameters of the process (*e.g.,* temperature of a compost pile) to ensure that they meet the conditions under which the process was validated. In addition, proposed § 112.54 would provide that the resulting biological soil amendments must be applied in accordance with the applicable application requirements in § 112.56. We seek comments on this approach.

The underlying framework for the provisions of §§ 112.54(a)–(c), 112.55, and 112.56 is that as the likelihood that a method of application of a biological soil amendment of animal origin will result in it contacting covered produce increases, the extent of measures taken to reduce the likelihood of known or reasonably foreseeable microbial hazards being present in the applied soil amendment must also increase. That is, for an application practice that is more likely to result in the amendment contacting covered produce (*e.g.,* broadcast application of a soil amendment vs. subsurface soil amendment injection for the same crop, or in-row application of a soil amendment for a row crop vs. in-row application for a tree crop), it is more important to have stricter controls for known or reasonably foreseeable microbial hazards in the applied soil amendment than for another amendment whose application practice is less likely to result in the amendment coming into contact with covered produce. Therefore, proposed § 112.54 consists of multiple acceptable options for the treatment of soil amendments and corresponding standards against which they are to be validated (as further described in § 112.55). These proposed treatment options were designed to be flexible to allow you to determine what your operation's needs are, and select the option that best fits those needs. In developing these proposed requirements, we have taken into account the wide variation presented by different feedstocks used in preparing biological soil amendments of animal origin, the diversity of commodities, and various growing regions. In addition, we considered the likelihood of contamination posed by biological soil amendments of animal origin subjected to each of these multiple treatment options when determining the appropriate application requirements, as proposed in § 112.56. We have tentatively concluded that the use of the physical, chemical, and composting treatments listed in proposed § 112.54(a)–(c), when applied in accordance with proposed § 112.56, are capable of adequately reducing pathogen levels in biological soil amendments of animal origin. We request comment on the appropriateness of each of the options considered, and discussion of any other options not listed in proposed § 112.54.

Physical treatments usually involve some form of high-heat treatment (cooking) of the biological soil amendment of animal origin to kill undesirable microorganisms. By contrast, chemical treatments usually involve greatly altering the pH of a biological soil amendment of animal origin, to the point that undesirable

microorganisms do not survive. In a study treating chicken manure with ammonia to reach high (alkaline) pH levels, a 3 to 4 log decrease of generic *E. coli* was observed over 6 days at 20°C, and drying manure to 10% moisture content and exposing it to ammonia gas (1% of manure wet weight) reduced pathogen load by 8 log (99.999999% reduction) (Ref. 181). To perform either physical or chemical treatments, the feedstock is generally placed in a large treatment container, and large amounts of energy are required in order to initiate the treatment. These factors alone make these forms of treatment impracticable for many farms. While such treatments can be expected to have a strong lethal impact on microorganisms present in the feedstock, they do not always result in complete elimination of pathogens. For example, chicken manure may be heat-treated to create a dried, pelleted material that is functionally sterile due to the high heat used during production; however, it has been observed that if the heat treatment is not uniform, the end product may still harbor human pathogens and pose a likelihood of the material being re-colonized by the microbial pathogen, leading to the possible contamination of any covered produce to which it is applied (Ref. 115).

Biological soil amendments of animal origin may also be prepared by combining multiple treatments, either alone or in combination. For example, a single feedstock may be heat-treated (physical) while also drenched in strong ammonia (chemical) to acidify the material (Ref. 182). Alternatively, feedstock may first be composted and then treated by heat to further reduce pathogens, effectively pasteurizing the material, as is common practice in the production of mushroom growth media (Ref. 183). These systems have been shown to be highly effective when proper controls are in place and monitored, but they also require significant inputs and capital investments.

Proposed § 112.54(a) would establish that a scientifically valid controlled physical process (*e.g.,* thermal), chemical process (*e.g.,* high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that have been demonstrated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes, Salmonella* spp., and *E. coli* O157:H7 is a treatment option for biological soil amendments of animal origin. This standard is currently used by the mushroom industry, which utilizes a two-phase process consisting of a composting treatment that meets the composting standard proposed in § 112.54(c) followed by a subsequent heating process that meets the microbial standard of proposed § 112.55(a). Together, the treatment reduces over 7 log cfu/g of *Listeria, Salmonella,* and *E. coli* O157:H7 to undetectable levels (Ref. 183). It also eliminates much of the native microflora (Ref. 183). We have tentatively concluded that a treatment meeting this standard would significantly reduce or eliminate known or reasonably foreseeable microbial hazards in biological soil amendments of animal origin, and would constitute the lowest expected likelihood of any of the proposed treatment options. We have also tentatively concluded that a biological soil amendment of animal origin that has been treated to this standard would be appropriate for use when the likelihood for contamination of covered produce is the highest, such as the substrate (growth media) used for growing mushrooms and some sprouts. Therefore, as provided in proposed § 112.56(a)(2) and discussed further in section V.F.2 f of this document, any biological soil amendment of animal origin treated to this standard would have the fewest limitations on its application.

Proposed § 112.54(b) would establish that a scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms is a treatment option for biological soil amendments of animal origin. We have tentatively concluded that a treatment meeting this standard would significantly reduce known or reasonably foreseeable microbial hazards in biological soil amendments of animal origin leading to minimal likelihood of contamination. A biological soil amendment of animal origin that has been treated to this standard would be appropriate for use when there is a high likelihood that the soil amendment will come into contact with covered produce. Moreover, as provided in proposed § 112.56 and discussed further in section V.F.2.f of this document, any biological soil amendment of animal origin treated to this standard would have minimal limitations on its application.

Proposed § 112.54(c) would establish that a scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms is a treatment option for biological soil amendments of animal origin. Two specific scientifically valid controlled composting processes that could be used to meet the requirements of proposed § 112.54(c) are provided: (1) Static composting that maintains aerobic (*i.e.,* oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 days and is followed by adequate curing, which includes proper insulation; and (2) turned composting to maintain aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation. These two composting processes are currently considered by the U.S. Environmental Protection Agency as Processes to Further Reduce Pathogens (Appendix B to 40 CFR part 503, part B.1). Both are recommended for use by the U.S. Department of Agriculture's Agricultural Research Service (Ref. 184), Natural Resources Conservation Service (Ref. 97), and National Organic Program (7 CFR part 205), and both are commonly accepted practices within the industry (Ref. 185). While there is robust discussion in the literature on times, temperatures, and other conditions (pH, moisture, oxygen levels, etc.) needed for significant reductions (albeit not elimination) of human pathogens in cattle, sheep and chicken manures, it is clear that composting cannot be considered as a pathogen-elimination step because of the many variables that can affect the efficacy of the composting process (*e.g.,* feedstock mixtures, climatic conditions, and various other physio-chemical parameters) (Ref. 174). These limits are currently used as composting endpoints by other federal agencies (40 CFR 503) States (Ref. 90. Ref. 164. Ref. 163), and industry (Ref. 31).

Composting is generally the least expensive method with the lowest capital investment requirement, and if properly managed, can be expected to significantly reduce pathogen populations in feedstock materials (Ref. 186). As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, composting has been shown to reduce the overall concentration of nitrogen in the soil amendment, which poses a concern for some farmers, but it also has been demonstrated that the remaining nitrogen is both in a more bio-available state (*i.e.,* more easily utilized by plants) and will persist in the environment for a longer time (therefore providing nutrients to plants for a longer time) (Ref. 27). Composting leaves much of the native microflora intact (Ref. 187).

Proper composting is not difficult for most operations, but it does require a labor commitment to ensure conditions are met and maintained to achieve the desired effect. Some of the most critical elements of composting include proper stacking of a pile, proper aeration and turning, and ensuring the pile attains the proper temperature and is allowed to cool (cure) for an adequate time (Ref. 27). There are currently no federally mandated composting standards for food safety. The USDA/NOP offers standards that are meant to maximize soil fertility in 7 CFR 205.203 (these are required to achieve ''USDA Certified Organic'' status, but otherwise are recommendations only), and EPA standards in 40 CFR part 503 are specific to sewage sludge, not animal manures. While these standards were not developed for food safety, several studies suggest that they would be appropriate for use as food safety measures (Ref. 27). Proper handling and storage during and after composting to avoid cross-contamination of cured product and in-process or raw product is critical, as discussed in section V.F.2.b of this document above regarding proposed § 112.52 of this rule. Other important factors in proper composting (such as the carbon to nitrogen ratio of the feedstock (C:N), the moisture content of the pile, the reaction to high cellulose-content material (*i.e.,* plant material such as straw or vegetative waste), and the specifics of the beneficial microbial content will vary depending on the feedstock (Ref. 187). The person who manages the composting process would also need to consider such factors as the moisture content, pH, carbon to nitrogen ratio (C:N), and feedstock to achieve the microbial standards set forth in proposed § 112.55. Many resources are available that discuss these details, such as the USDA NRCS handbook (Ref. 97). When composting processes are carried out in an incorrect manner, the organic matter in the finished product remains poorly stabilized and recontamination is more likely to occur, which can potentially result in the compost becoming a source of pathogens that could contaminate the field to which it is applied and any crops that are grown in the amended soil (Ref. 165).

As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, adequate curing, including proper insulation (usually consisting of around one foot thick of insulating material, *e.g.,* hay, straw, finished compost) is included as part of this proposed requirement, because curing is an important step in the composting process to further reduce the levels of pathogens, complete the chemical reactions of composting, and mitigate the impact that incomplete turning (creating temperature stratification within an active pile) would have on composting efficacy (Ref. 27). Proper insulation serves as a layer of protection from external influences (*e.g.,* temperature changes, wild animal encroachment).

The treatment processes proposed in § 112.54(c), paragraphs (1) and (2), may not be the only means of achieving adequate composting to meet the microbial standards in proposed § 112.55(b). Therefore, we have tentatively concluded that it would be appropriate to allow for the use of static or turned composting protocols other than those specified in § 112.54(c)(1) and (2), if they meet the microbial standards for validation for composting in proposed § 112.55(b). Proposed § 112.54(c)(3) allows for the use of other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative has been demonstrated to satisfy the microbial standard in § 112.55(b). No such alternatives are provided for the treatment requirements of § 112.54(a) and 112.54(b), because those parts do not explicitly define the processes to be conducted to meet the microbial standards presented; therefore, any scientifically valid controlled physical, chemical, or combination of physical and chemical processes that has been demonstrated to satisfy the relevant microbial standard in either § 112.55(a), or § 112.55(b) will meet the requirements of those subparts.

e. Microbial Standards Applicable to Treatment Processes

Proposed § 112.55 establishes microbial standards applicable to the treatment processes in § 112.54. Proposed § 112.55(a) would provide microbial standards for the treatment process in proposed § 112.54(a). It would require: (1) *L. monocytogenes* to be not detectable using a method that can detect one colony forming unit (CFU) per five gram analytical portion; (2) *Salmonella* spp. to be less than 3 most probable number (MPN) per four grams of total solids (dry weight basis); and (3) *E. coli* O157:H7 to be less than 0.3 MPN per 1 gram analytical portion. As discussed immediately above regarding proposed § 112.54(a), these standards are the most stringent and meant for applications in which a biological soil amendment of animal origin would otherwise pose the greatest likelihood of transferring a known or reasonably foreseeable hazard to a covered produce commodity. These standards would also be useful if you wanted to use a biological soil amendment of animal origin with the least amount of application restrictions available under proposed § 112.56. As previously noted, these microbial standards are currently used by the mushroom industry for growth media and reduce over 7 log CFU/g of *Listeria, Salmonella,* and *E. coli* O157:H7 to undetectable levels (Ref. 183).

Proposed § 112.55(b) would provide two microbial standards, both of which must be satisfied for the treatment processes in proposed § 112.54(b) and (c). This section would require less than 3 MPN *Salmonella* spp. per 4 grams of total solids (dry weight basis), and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis). These limits are currently used as composting validation endpoints by EPA (40 CFR 503), some States (Ref. 90. Ref. 164. Ref. 163), and industry (Ref. 31). Ohio and California (Ref. 163. Ref. 164), industry (Ref. 31) and other nations such as Canada and the United Kingdom (Ref. 27) use both of these criteria, while EPA and Florida (Ref. 92. Ref. 90) allow for either criteria to be used. As noted in the Produce Safety Project Issue Brief on Composting of Animal Manures, the EPA requirement of validation with either Salmonella spp. or fecal coliforms is based on the observation that reduction in fecal coliforms is well correlated to reduction in *Salmonella* spp. when biosolids are composted (Ref. 27). However, we tentatively conclude that satisfying both of these criteria is necessary to significantly minimize known or reasonably foreseeable hazards when combined with the applicable application requirements in proposed § 112.56. Monitoring the relative levels of indicator microbes such as fecal coliforms, which are predominantly *E. coli* in manures and freshly mixed compost, is advantageous in that they are abundant in manure. In the absence of a reliably present pathogen, fecal coliforms are useful to validate the efficiency of the thermophilic composting process (Ref. 27). Additionally, *E. coli,* the primary fecal coliform in manure, has been documented to be a good indicator of the inactivation of *E. coli* O157:H7 (Ref. 168). Validating solely with *Salmonella* spp. is not sufficiently protective or useful for validating the efficiency of a thermophilic composting process, since Salmonella spp. cannot be assumed to be present in all composting feedstock materials. On the other hand,

Salmonella spp. is the most common microbiological hazard associated with fresh produce (Ref. 3). As such, validating with fecal coliforms and *Salmonella* spp. not only assures the efficacy of the thermophilic composting process but also assures significant reduction of the pathogen *Salmonella* spp. when commonly used compost feedstocks are used that are likely sources of Salmonella spp. (*e.g.,* cattle and poultry manure) (Ref. 188). We seek comment on these proposed microbial standards and potential alternatives.

We do not intend this proposed provision to require that farms test their treated biological soil amendments for compliance with the microbial standards. Rather, we intend this provision to provide the standard against which treatment processes must be validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard in this section without needing to test the end products of their treatments to confirm that the microbial standard was achieved.

f. Application Requirements and Minimum Application Intervals

Proposed § 112.56 establishes the application requirements and minimum application intervals applicable to biological soil amendments of animal origin. Proposed § 112.56(a) would establish a requirement that, except as provided in subparagraph (b), any biological soil amendment of animal origin that you use must be applied with the application method requirements and minimum application intervals specified in the table presenting proposed § 112.56(a)(1)–(4). The different application method requirements and intervals for biological soil amendments of animal origin are presented so that you may determine the amendment, application, and interval that is most appropriate for your situation, based on the expected likelihood of contaminating produce by use of the biological soil amendment of animal origin you plan to use.

In developing the application methods requirements of proposed § 112.56(a)(1)–(4), we first considered specifications of each type of biological soil amendment of animal origin, and then considered the likelihood that the soil amendment will come into contact with covered produce. For example, those biological soil amendments of animal origin treated with a process or processes capable of consistently and reliably reducing or eliminating pathogens as per § 112.54(a) do not have any application restrictions, and may come into contact with covered produce during harvest and growing (proposed § 112.56(a)(2)), such as in the growing of mushrooms and some sprouts. Conversely, those treatments that are expected to have some likelihood of harboring significant numbers of human pathogens, *i.e.,* those treated in accordance with the requirements of § 112.54(b) or (c), have proposed limitations on the method of application that minimize the potential for the treated biological soil amendment of animal origin to contact covered produce during and after application (proposed § 112.56(a)(3), (a)(4)(ii)) and also allow for pathogen die-off when it is reasonably likely that covered produce will contact soil after application of the soil amendment (proposed § 112.56(a)(4)(i)). Requirements would include the application of untreated biological soil amendments of animal origin in situations where it is reasonably likely that covered produce will contact the soil after application of the soil amendment (§ 112.56(a)(1)(i)), where the amendment would be permitted to be applied in a manner that minimizes the potential for contact with covered produce after application, but with an additional food safety measure that it can be applied only in a manner that does not contact covered produce during application and using a minimum application interval of 9 months. By contrast, in situations where covered produce will not contact the soil, (§ 112.56(a)(1)(ii)), the amendment would be permitted to be applied without an application interval. We explain each of these proposals in detail below.

Proposed § 112.56(a)(1)(i) requires that if you apply a biological soil amendment of animal origin that is untreated, then the material must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application and the minimum application interval is nine (9) months. This provision would apply to any situation in which the covered produce is reasonably likely to contact the soil after application of the soil amendment. Proposed § 112.56(a)(1)(ii) requires that if you apply a biological soil amendment of animal origin that is untreated, and the material is applied in a manner that does not contact covered produce during or after application, there is no minimum application interval. This provision would apply to any situation in which the covered produce will not contact the soil after application of the soil amendment. The specific microbial populations of raw manure are generally unknown, but can be expected to be very high, and are likely to include zoonotic microorganisms that pose a food safety hazard (such as *Salmonella* spp. up to 10^7 (Ref. 176) and *E. coli* O157:H7 up to 10^6 (Ref. 189)). Based on our QAR, we have determined that raw animal waste (manure, litter, mortalities, etc.) is likely to contain human pathogens and has the highest likelihood of contaminating covered produce. Therefore, we tentatively conclude that such material should only be used where, and in a manner, that such likelihood is minimized. As discussed above, the likelihood of produce contamination by an agricultural tea that contains agricultural tea additives is also high (Ref. 142). Given the desire to both allow for the continued use of raw manure, agricultural teas containing agricultural tea additives, and other untreated biological soil amendments of animal origin; and to minimize the risk of known and reasonably foreseeable hazards, we have tentatively concluded that we should require that untreated biological soil amendment of animal origin (including raw manure) applied in the growing of covered produce should either first be treated to reduce microbial food safety hazards; or if the covered produce is reasonably likely to contact the soil after application of the soil amendment, the untreated soil amendment should be applied in a manner that keeps it from coming into contact with covered produce during application, minimizes the potential for contact after application, and allows for the die-off of pathogens; and if the covered produce will not contact the soil after application of the soil amendment, the untreated soil amendment should be applied in a manner that keeps it from coming into contact with covered produce during and after application. In the case of agricultural teas containing agricultural tea additives, we tentatively conclude that because additional treatment is not an option they should be applied in the same manner as untreated biological soil amendments of animal origin. Proposed § 112.56(a)(1)(i) would therefore establish such restrictions on the manner of application for these materials when they are reasonably likely to come in contact with covered produce after application, as well as a minimum application interval (waiting period) of nine (9) months from the application of untreated biological soil amendments of animal origin to the harvest of covered produce. On the

other hand, under proposed § 112.56(a)(1)(ii), untreated biological soil amendments of animal origin would be permitted for use with no minimum waiting period when the soil amendment is applied in a manner that does not contact covered produce during or after application. We investigated the potential for survival of many enteric pathogens of public health concern (Ref. 190. Ref. 92) and determined that across various pathogens and their potential environments, pathogen survival and die-off time in soils amended with raw manures are extremely varied. One consistency across many trials was an observed rapid early die off of many pathogens, followed by a prolonged survival of the remaining low populations (Ref. 191. Ref. 104. Ref. 192). It is unclear in the existing literature at what point the population is low enough to minimize the potential for contamination of covered produce; it is reasonable to suggest that once pathogen populations fall below detection limits, their risks are minimized.

Some of the longest survival times involved organisms initially present at very high initial populations (*e.g., E. coli* O157:H7 in sheep manure (Ref. 177) surviving for 21 months) or involved certain pathogens such as encysting parasites (*Cryptosporidium parvum* cysts surviving for over a year (Ref. 193) or the eggs of parasitic flatworms (*Ascaris* ova surviving for over 15 years (Ref. 174)). Some enteric pathogens are reported to be more resilient to deleterious effects of the environment than others (most notably, *Salmonella* seems better attuned for survival outside of a host than does *E. coli* O157:H7 (Ref. 194)) and those microorganisms that produce spores are especially hardy. Basing all manure application standards on these extreme cases would be unnecessary. The majority of survival studies showed that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year (Ref. 190). This includes organisms less commonly associated with fresh produce, such *Cryptosporidium, Giardia,* and *Ascaris* (parasitic flat worms). Organisms most commonly associated with fresh produce outbreaks (such as *E. coli, Salmonella* and *Listeria*) are unlikely to survive at detectable population levels in soil past 270 days (Ref. 181. Ref. 182. Ref. 183). Therefore, we tentatively conclude that utilizing a 9-month waiting period between the application of untreated biological soil amendment of animal origin and the harvest of covered produce would be protective for the preponderance of environments in situations where covered produce is reasonably likely to contact the soil after application of untreated biological soil amendments of animal origin. This is not inconsistent with the 12-month restriction used by some segments of the produce industry (Ref. 31). Where the soil amendment does not contact covered produce either during or after application, we do not believe that a minimum application interval is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce. Therefore, proposed § 112.56(a)(1)(ii) provides for the option to use untreated biological soil amendments of animal origin with no minimum waiting period, provided the soil amendment is applied in a manner that does not contact covered produce during or after application. We seek comment on the proposed waiting period.

One study, which specifically addressed considerations of microbial survival in soil and resulting transfer on to produce grown in the soil, suggested that, under ideal conditions for survival, organisms could survive for greater than 226 days (Ref. 191). The study was performed in the Southeastern U.S. (Georgia) and, therefore, is unlikely to reflect climatic conditions prevalent in other areas of the country, including the potential for the ground to freeze during winter. While microbes present on frozen ground can be expected to be reduced in population more rapidly (Ref. 195), those surviving are likely to persist for a longer time period in a state of dormancy (Ref. 196). The dormancy of microorganisms also means that they will pose a likelihood of contamination for greater periods of time, creating a wider window of opportunity for covered produce to become contaminated. We request comment on whether and how, as an additional requirement for the application of untreated biological soil amendments of animal origin, the time period when the soil is frozen should count toward the proposed application interval. Further, it has been noted that rapid freeze-thaw cycles of weather may cause more rapid die-off rates of pathogens present in soils (Ref. 197). We request comment on the impact that freeze-thaw cycles may have on use of biological soil amendments of animal origin.

Proposed § 112.56(a)(2) would establish that the use of a biological soil amendment of animal origin treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a), would have no application method restrictions and no minimum application interval. At this level of microbial reduction, a treated biological soil amendment of animal origin can be expected to present negligible likelihood of contamination. Therefore, we have tentatively concluded that no further action is necessary for the safe use of such a product in conjunction with covered produce.

For example, unlike other biological soil amendments of animal origin, the nature of a growth medium that is a biological soil amendment of animal origin and is used for growing mushrooms, some sprouts and similarly grown produce, makes contact between the covered produce and the growth medium inevitable. This precludes the ability to utilize application restrictions as a meaningful measure to minimize the likelihood of pathogen contamination of covered produce through a multiple-hurdle approach, that would allow for the use of less robust treatment processes in combination with application manner restrictions. Therefore, we tentatively conclude that, such growth media must be treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).

As proposed, § 112.56(a)(3) would require that a biological soil amendment of animal origin treated by a scientifically valid controlled physical or chemical process, or a combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b) be used in a manner that minimizes the potential for contact with covered produce during and after application, with no minimum application interval. We have tentatively concluded that treating a biological soil amendment of animal origin to meet the standards of § 112.54(b) would significantly decrease the population of any microorganisms of public health significance that may have previously been present. Further, the proposed application restriction of minimizing direct contact of the amendment with the edible portion of covered produce would further reduce the likelihood of any remaining microorganisms in a treated soil amendment contaminating covered produce, as well as reduce the

likelihood that the soil amendment would provide a nutrient source for any microorganisms of public health significance already present on covered produce. We have tentatively concluded that the treatment of the biological soil amendment of animal origin, combined with minimizing its contact with covered produce would adequately reduce the likelihood of contamination and subsequent severe adverse health consequences or death. We have also tentatively concluded that, with the likelihood already minimized, it is unnecessary to implement a further burden by proposing a minimum application interval for soil amendments treated by physical or chemical processes, or combinations of such processes, to the standards of § 112.54(b). For example, chicken manure pellets that have been treated by a controlled high-temperature process according to a protocol that has been validated to meet the standards in proposed § 112.54(b) could be used as an in-furrow side-dress for leafy greens immediately before harvest. However, in this same example, the application could not be conducted by overhead broadcast spreading, since this method would not minimize contact of the biological soil amendment with the covered produce.

Proposed § 112.56(a)(4)(i) would establish requirements for use of a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) in a manner that minimizes the potential for contact with covered produce during and after application and with a minimum application interval of 45 days. This provision would apply to situations in which the covered produce is reasonably likely to contact the soil after application of the soil amendment.

Proposed § 112.56(a)(4)(ii) requires that if you apply a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), and the material is applied in a manner that does not contact covered produce during or after application, there is no minimum application interval. This provision would apply to any situation in which the covered produce will not contact the soil after application of the soil amendment. Although the microbial standards and application restrictions for biological soil amendments of animal origin treated to meet the requirements of proposed § 112.56(a)(4) are the same as those described under proposed § 112.56(a)(3), there is an additional 45 day application interval for § 112.56(a)(4)(i) that would not be required in § 112.56(a)(3). We have tentatively concluded that process controls during chemical or physical treatments can be expected to be less prone to failure than process controls for composting. For example, heat treatments are often conducted in enclosed heat-treatment chambers (*i.e.,* ovens), often with various means of agitation (such as stirring rods, etc.), that can be accurately monitored and controlled to reach the required treatment conditions throughout the material being treated. Conversely, composting usually occurs outdoors, is exposed to fluctuating environmental pressures and wildlife activity, is not homogeneous in nature and prone to having ''cold-spots'' that are not completely treated (even with proper turning) (Ref. 174). In general, in composting, there is a higher likelihood of having a systems failure, which is also more likely to go undetected, should it occur. Composting may result in a treated biological soil amendment of animal origin that may continue to harbor human pathogens of food safety concern (Ref. 174), although any such hazards that may be present can be expected to be present at low populations and unlikely to survive for extended periods under normal environmental conditions after application. Examples of a system failure that may occur during composting, but would not be expected during a thermal or physical treatment, could include animal intrusion, incomplete turning, or reduced efficiency of composting due to environmental or climatic conditions (*e.g.,* heavy rainfall or excessive cloud cover reducing the temperature of the pile or portions of the pile). Therefore, we propose to impose an additional mitigation measure in situations where covered produce is reasonably likely to contact the soil after application of biological soil amendments of animal origin treated by composting by requiring a minimum application interval of 45 days. This time period has been shown to be effective when the population of the pathogen is minimal (Ref. 92. Ref. 91) (Ref. 198), as can be expected of a fully composted biological soil amendment of animal origin. This multiple hurdle approach and time interval has also been utilized in a current industry standard (Ref. 31). Where a biological soil amendment of animal origin does not contact covered produce either during or after application, we do not believe that a minimum application interval is reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce. Therefore, proposed § 112.56(a)(4)(ii) provides for the option to use a biological soil amendment of animal origin treated by composting with no minimum waiting period, provided the soil amendment is applied in a manner that does not contact covered produce during or after application. We seek comment on the appropriateness of the proposed application period intervals.

We have not proposed any provisions specific to the status of spent mushroom mulch (growth media already used in the production of mushrooms for subsequent use as a biological soil amendment of animal origin in the growing of other covered produce) and specifically request comment on how to classify its status. The practice of storing spent mushroom mulch for subsequent use in the growing of covered produce is not known to be a likely source of introduced contamination because the growth media would have been previously treated to eliminate pathogens (Ref. 62). Therefore, we tentatively conclude that spent mushroom mulch previously treated (in accordance with proposed § 112.54(a), to meet the microbial standards of § 112.55(a)) before use in the growing of mushrooms would still be considered as ''treated'' to meet the standards of § 112.54(c) after use for growing mushrooms, and for any possible subsequent use in the growing of fresh produce without any intervening treatment, unless you know or have reason to believe it has been otherwise contaminated with a hazard or has been associated with foodborne illness. We tentatively conclude that spent mushroom mulch should be considered, for the purpose of the application requirements in proposed § 112.56, as though it has been treated by composting, instead of considering it as though it has been treated in accordance with the most robust chemical/physical treatment process (§ 112.54(a)), though it would have received such a treatment in accordance with proposed § 112.54(a) before its use to grow mushrooms. This would have the effect of subjecting spent mushroom mulch used subsequently to grow other covered produce to the requirement to minimize the potential for contact with covered produce during and after application, and a minimum application interval of 45 days. We consider the weathering process (the common practice of spent mushroom mulch being placed in a field

in windrow for further composting over the course of several weeks to years) to be similar to composting in terms of likelihood of introduction of contaminants. We request comment on this tentative conclusion.

Under this proposal, you would, in most cases, maintain the flexibility to choose among a variety of treated and untreated soil amendments of animal origin based on the commodity being grown, growing conditions, and other factors relevant to your operation, but you would have to consider both the method of application (*e.g.,* whether it would result in contact between the amendment and the produce) and, for certain amendments, the interval before harvest. We would expect you to determine which application method is most appropriate for your situation by selecting the application method and interval restrictions that would coincide best with your operation, and then purchase or treat a biological soil amendment of animal origin that meets the corresponding specifications (*i.e.,* the first column in the table in § 112.56(a)). For example, if you intend to apply a side-dress of a biological soil amendment of animal origin close to harvest, you would find § 112.56(a)(1)(ii), (2), (3), and (4)(ii) have no minimum application interval. You would accordingly either use a controlled physical or chemical process that meets the requirements of § 112.54(a) and have no further restrictions, use a controlled physical or chemical process that meets the less stringent microbial standards of § 112.54(b) if you can apply the treated biological soil amendment of animal origin in a manner that minimizes potential for contact with the covered produce during and after application, or use composted or untreated biological soil amendments of animal origin if you can apply them in a manner that ensures they do not contact covered produce during or after application (for example, if you are growing tree crops such as oranges, you apply the untreated soil amendment without causing it to contact the oranges, and you do not harvest oranges that have been allowed to come into contact with the soil after application of the soil amendment). Conversely, you may determine which application method and interval is most appropriate by evaluating which specification your biological soil amendment of animal origin meets, and then apply it according to the coinciding application method and interval restrictions. If, for example, you wish to apply raw manure to your field, you would find the requirements that apply to raw manure in § 112.56(a)(1) and note that, if it is reasonably likely that your covered produce will come in contact with the soil (for example, where almonds are harvested by intentionally dropping to the ground) after application of the raw manure, the use of raw manure is restricted to application in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and may be applied no less than 9 months before harvest. On the other hand, if you can apply the raw manure in a manner that ensures it does not contact covered produce during or after application, you may use it without a minimum application interval. Any minimum application interval that you use can be concurrent with any application intervals that you are already required to, or voluntarily, apply. For example, if you are a USDA-certified organic grower, and utilize a 120-day application interval for the use of raw manure as part of participation in the National Organic Program, the proposed 9-month application interval requirement in § 112.56(a)(1)(i) would be concurrent, not consecutive, with the 120 days. Thus, your use of a 9-month application interval for raw manure would satisfy both this proposed rule and the requirements of the National Organic Program. As another example, if you plan to apply a biological soil amendment of animal origin to a field of spinach that is nearing harvest for fresh market consumption, assuming the spinach is reasonably likely to contact the soil after application of the soil amendment, you could select a biological soil amendment of animal origin that is heat-treated to meet the standards presented in § 112.54(b) (*e.g.,* chicken manure pellets), provided that you can apply it in a manner that minimizes the potential for contact with covered produce during and after application (*e.g.,* used as a side-dressing), because there would not be an application restriction interval with that type of biological soil amendment of animal origin. If you plan to use manure as a biological soil amendment of animal origin for the same crop and plan to apply the amendment before planting, and do not wish to utilize a treatment such as described by § 112.54(a) or (b), you would choose to compost the soil amendment to meet the requirements of § 112.54(c). Use of such a biological soil amendment of animal origin would only be restricted to application in a manner that minimizes the potential for contact with covered produce during and after application, and application at least 45 days prior to harvest.

Proposed § 112.56(b) would establish requirements for the use of alternatives to the minimum application intervals established in paragraphs (a)(1)(a) and (4)(a) of proposed § 112.56, provided you satisfy the requirements of § 112.12. We have tentatively concluded that, under certain circumstances, an alternative standard may be appropriate if it is shown to provide the same level of public health protection as the standard in proposed § 112.56(a)(1)(i) and (4)(a) and not to increase the likelihood that the covered produce will be adulterated. For example, alternatives to the proposed minimum application intervals could take into account specific characteristics of the locality, crop and the agro-ecological environment. Such alternatives could consider differences in feedstock; application methods; and treatment methods, especially given the potential for new innovations in such methods. In any such case, as discussed below, we propose in § 112.60(b)(5) that you establish and keep documentation of the scientific data and information you are relying on to support the use of an alternative minimum application interval. We do not propose that you would be required to submit such data and information to us for prior approval; we do, however, propose the requirement that you maintain a record of any such data and information for us to evaluate upon request.

h. Records Requirements

Proposed § 112.60(a) requires that you establish and keep records for subpart F in accordance with the requirements of subpart O of this part. Proposed § 112.60(b) would establish requirements for records you must establish and keep regarding biological soil amendments of animal origin that you use. Proposed § 112.60(b)(1) would require documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment. These records would be required because the application of both raw manure and compost include minimum application intervals (§ 112.56(a)(1)(i) and (4)(i), respectively), so it would enable FDA to verify compliance with the application intervals associated with raw manure

and compost. These records would also allow you to keep track of the dates on which those biological soil amendments of animal origin were applied in order to determine when covered produce from those growing areas could be harvested in compliance with the rule. USDA-certified organic growers who already maintain records of when biological soil amendments of animal origin are applied in compliance with 7 CFR 205.103 would not need to duplicate those records to meet the requirements of § 112.60(b)(1).

Proposed § 112.60(b)(2) would require documentation (such as a Certificate of Conformance) for a treated biological soil amendment of animal origin that you receive from a third party. We have tentatively concluded that the information you will need both to verify that any biological soil amendment of animal origin you purchase for use in performing a covered activity is in compliance with this subpart F, and to inform your decisions on further handling, conveying, and storing of the purchased biological soil amendment of animal origin, includes the following: (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; (ii) the applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and (iii) the biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the likelihood of contamination by an untreated or in-process biological soil amendment of animal origin. Aspects (i) and (iii) of this proposed requirement reflect information that you would have if you treated the biological soil amendment of animal origin on your own farm in accordance with this proposed rule. Aspect (ii) of this requirement would provide you with reasonable assurances that your supplier is carrying out the applicable treatment process in an effective manner such that the biological soil amendment of animal origin that you purchase meets the applicable standards in proposed §§ 112.54 and 112.55. We tentatively conclude that it is appropriate to require this additional level of assurance from your suppliers in order to allow FDA to verify your compliance with these requirements. These requirements will also provide you with a comparable level of control over your supplier's process of treating a biological soil amendment of animal origin as you would have if you were to apply the treatment process on-farm, where you would be able to monitor the process controls yourself. You would not be required to perform any treatment processes on a biological soil amendment of animal origin that you purchase and for which you have the appropriate documentation showing it has already been treated by a validated process in accordance with § 112.55. These records would also allow you to ensure that a treated biological soil amendment that you purchase from a third party meets the requirements of this proposed rule and to determine the relevant application restrictions you must apply to such a soil amendment.

Proposed § 112.60(b)(3) would require documentation that process controls (for example, time, temperature and turnings) were achieved for any treated biological soil amendment of animal origin you produce for your own covered farms. This documentation is required to verify that the treatment or treatments you performed were properly carried out. For example, such records would inform you of any breakdown in the process or treatments, how they occurred or can be corrected, and create a history to help you predict and prevent any future breakdowns. Without such records, you would not be able to ensure, and we would not be able to verify, that the process or treatment you performed achieved the required parameters that are validated to meet the microbial standards of § 112.55 or that the alternatives that you are using (if applicable) satisfy the requirements of proposed § 112.12.

Proposed § 112.60(b)(4) would require documentation of scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3). Similarly, proposed § 112.60(b)(5) would require documentation of scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b). The records described in § 112.60(b)(4) and (5) would be required only if you choose to use alternatives to those processes presented in § 112.54(c)(1) and (c)(2) or application intervals in § 112.56(a)(1)(i) and (a)(4)(i), respectively. This documentation would be required so that, as necessary, we are able to verify that use of your alternative process achieves the required parameters of proposed subpart F and satisfies the requirements of proposed § 112.12.

Finally, we seek comment on an issue that is not explicitly addressed in our proposed provisions. Biological soil amendments (including agricultural teas derived from biological materials) are nutrient rich and may support rapid and prolific growth of human pathogens, if pathogens are present. Seeds used for sprouting have repeatedly been demonstrated to have the potential to be contaminated with human pathogens and cause human illnesses. We note that the National Organic Standards Board Compost Tea Task Force recommended not allowing for the use of ''compost tea'' for the production of edible seed sprouts (Ref. 36). We are concerned that using a biological soil amendment (including agricultural teas derived from biological materials) could increase the likelihood of rapid and prolific growth of human pathogens, if present, during sprout growing. We request comment on whether sprouters currently use biological soil amendments (including agricultural teas made from biological materials, such as ''compost teas'') in the growing of sprouts. In addition, we request comment on the likelihood of contamination presented by such a practice and whether the practice should be prohibited.

G. Subpart G—We Have Tentatively Reserved Subpart G of This Proposed Rule

H. Subpart H—We Have Tentatively Reserved Subpart H of This Proposed Rule

I. Subpart I—Standards Directed to Domesticated and Wild Animals

As proposed, subpart I provides science-based minimum standards that are directed to domesticated and wild animals and are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Related to Proposed Provisions

We received several comments in response to the 2010 FR notice that addressed issues relevant to standards directed to domesticated and wild animals. Some comments expressed concern about requiring measures that prohibit the use of domesticated work animals on farms. Some comments

asserted that monitoring wildlife in a farm environment is untenable, whereas other comments recommended that we prepare a list of ''animals of concern'' to enable farmers to know where to target preventive controls for domesticated and wild animals. Some comments recommended that sustainable conservation practices should be adopted and recognized as enhancing food safety. Several comments noted that farmers are subject to State and Federal laws regarding wildlife (*e.g.,* Endangered Species Act and Clean Water Act) and that there are programs that emphasize environmental stewardship (*e.g.,* National Organic Program and programs of the Natural Resources Conservation Service). Others expressed concern about any requirements that would lead to destruction of habitat or clearing of farm borders.

This proposed rule would not prohibit the use of on-farm domesticated working animals. Rather, this proposed rule would require you to take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce, if you use working animals in a growing area where a crop has been planted and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We disagree with comments that asserted that monitoring for animal intrusion is untenable. Periodic monitoring for animal intrusion and deposition of their excreta is a necessary measure to prevent contamination of covered produce with biological food safety hazards when there is a reasonable probability that animals will contaminate covered produce. We consider that monitoring during the growing season and immediately prior to harvest is a practical and minimum necessary standard to sufficiently ensure that any potential hazards related to animal intrusion are identified for appropriate follow-up actions in these situations. Proposed § 112.83 is intended to provide you with information about animal movements on your farm, allow you to recognize significant intrusion, and facilitate your taking appropriate measures following significant animal intrusion.

While we recognize the value of establishing a list of ''animals of concern,'' we tentatively conclude that current scientific evidence on the extent to which specific animals present the greatest risk for pathogens is inadequate to develop such a list. Moreover, data on regional and seasonal variations in the prevalence of pathogens in different kinds of animals are scarce. We encourage the application of practices that can enhance food safety, including sustainable conservation practices. A set of examples of biodiversity and conservation practices that may enhance food safety is available from the Resource Conservation District of Monterey County, CA (Ref. 199). This proposed rule would not require the destruction of habitat or the clearing of farm borders. Instead, we propose to require you to monitor those areas that are used for a covered activity for evidence of animal intrusion when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

2. Proposed Requirements

Proposed subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. Proposed subpart I would not be directed to the potential for biological hazards from manure that may be used as a soil amendment; such requirements directed to biological soil amendments of animal origin are discussed in section V.F of this document.

Consistent with sections 419(a)(1)(A), 419(a)(3)(E), and 419(a)(3)(D) of the Act, we consulted with USDA's National Organic Program and Natural Resources Conservation Service, U.S. Fish and Wildlife Service, and the EPA (Ref. 115) to ensure that environmental and conservation standards and policies established by those agencies are appropriately considered in developing the requirements proposed in this subpart. Based on these consultations, we tentatively conclude that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the National Organic Program. In addition, also based on these consultations, we tentatively conclude that the provisions of proposed subpart I are consistent with existing conservation and environmental practice standards and policies while providing for enforceable public health protection measures. Furthermore, the provisions in proposed subpart I are consistent with current recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), Commodity-specific industry guidances (Ref. 44. Ref. 46), and the LGMA (Ref. 31). We seek comment on the interactions of the proposed rule with the National Organic Program and opportunities to streamline compliance with both programs.

We acknowledge the longstanding co-location of animals and plant food production in agriculture. However, as discussed in the QAR, both wild and domestic animals may be a source of human pathogens. In fact, domesticated animals, due to their close proximity and interaction with humans, are generally more likely to harbor zoonotic pathogens than are wild animals (Ref. 200). Therefore we tentatively conclude that measures should be taken to minimize the likelihood of covered produce being contaminated by excreta from grazing and working animals. The likelihood of contaminating fresh produce with human pathogens from excreta from grazing and working animals is determined by numerous factors, including but not limited to the species of the animal, the number of animals per unit area of land, agro-ecological conditions, and the time period between animal grazing or working in fields and the harvest of fresh produce (Ref. 176. Ref. 169. Ref. 201. Ref. 202).

Proposed § 112.81(a) would establish that the requirements of proposed subpart I apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We have tentatively concluded that measures directed to domesticated and wild animals (such as cows, swine, and deer) are necessary when a covered activity takes place in an outdoor area or a partially-enclosed building if, under the circumstances, there is a reasonable probability that animals will contaminate covered produce, because it is reasonably likely that such animals will encroach on such areas and deposit excreta on covered produce or food contact surfaces. Some human pathogens of public health concern (*e.g., E. coli* O157:H7) that have been associated with produce foodborne outbreaks are zoonotic, meaning that they may originate from animals as well as humans. Therefore, animals, both wild and domestic, may be a source of human pathogens during the growing, harvesting, packing and holding of covered produce. We expect this provision to provide flexibility for farmers to consider the nature of covered produce and covered activities (including characteristics of covered produce) in light of the potential for contamination, and determine whether

the proposed requirements of subpart I would be applicable under the circumstances. For example, in the case of covered produce that grows completely underground, we expect that there would not be a reasonable probability of contamination of covered produce by domesticated or wild animals that may graze on or encroach into fields. The proposed requirements in §§ 112.82 and 112.83, therefore, would not apply to covered activities taking place in an outdoor area or a partially-enclosed building when such activities relate to covered produce that grows completely underground. We note, however, that we do not intend the phrase ''under the circumstances'' in these proposed requirements to suggest that farms alter their surrounding environment in order to reduce the chances of animal intrusion, such as by clearing farm borders around outdoor growing areas or drainages. This proposed rule is not intended to require such actions. We intend the phrase ''under the circumstances'' to refer to the nature of the covered produce (such as its growth habit) and the nature of covered activities (such as the manner in which working animals are used in growing areas). We request comment on this issue.

Proposed § 112.81(b) would provide that the provisions of proposed subpart I would not apply to fully enclosed buildings. We tentatively conclude that the measures proposed in this section directed to domesticated and wild animals (such as cows, dogs, swine, and deer) are not necessary when a covered activity takes place in a fully-enclosed building. Rather, we propose measures directed at domesticated and wild animals (such as horses, dogs, and rodents) in a fully-enclosed building in proposed § 112.127 (see section V.L. of this document).

Proposed § 112.82 would establish requirements for measures that you must take, at a minimum, if you allow animals to graze or use them as working animals in fields where you grow covered produce and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce. Proposed § 112.82(a) would require you to implement an adequate waiting period between grazing and time of harvest for covered produce in any growing area that was grazed, to ensure the safety of the harvested crop. The potential likelihood of animals to act as vectors of human pathogens is determined by several factors, including but not limited to the type of commodity (as discussed above), and the species of the animal and its association with human or domesticated animal activity or waste (Ref. 199). A suitable time period based on these and other relevant factors must be established for the purpose of reducing, via die-off, pathogen levels in the excreta that may be transferred to covered produce. We would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment in proposed § 112.56(a)(1)(i).

Proposed § 112.82(b) would require that, if you use working animals in a growing area where a crop has been planted, you must take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce. For example, if you use draft horses as working animals in your covered produce fields, you could establish and use horse paths which are segregated from covered produce plantings, and minimize entry of the horses into covered produce plantings, thus minimizing the opportunity for horse excreta to contact covered produce or food contact surfaces.

Proposed § 112.83 would establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce. We are proposing to require that you monitor these areas as needed throughout the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). In proposed § 112.83(b) we would also require that, if animal intrusion occurs, as evidenced by observation of significant quantities of animals, animal excreta or crop destruction via grazing, you must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112.

We acknowledge that when covered produce is grown in an outdoor environment, wild animals are likely to have access to production fields. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk. However, wild animals are known zoonotic disease reservoirs for human pathogens, and therefore their excreta may contaminate growing covered produce crops (Ref. 169. Ref. 203). Monitoring immediately prior to harvest will enable you to identify instances when covered produce cannot be safely harvested, such as when it is not possible to effectively avoid the harvest of covered produce that was directly exposed to animal excreta or that may be cross-contaminated during harvest (*e.g.,* contamination of covered produce by contact with a food-contact surface that contacted animal excreta), as provided for in proposed § 112.112.

Monitoring throughout the growing season may assist you in developing an understanding of when and the degree to which animal intrusion occurs throughout the production season from planting to harvest. This proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

J. Subpart J—We Have Tentatively Reserved Subpart J of This Proposed Rule

K. Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding Activities

As proposed, subpart K discusses science-based minimum standards directed to growing, harvesting, packing, and holding activities that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

1. Comments Relevant to the Proposed Provisions

We received some comments in response to the 2010 FR notice that addressed the adequacy and cleanliness of food-packing material and requested that reusable containers be allowed in packing produce commodities.

It is important to ensure that food-packing material that is used in covered activities is adequate for its intended use, including that it is clean. In proposed § 112.116 below, we address the adequacy and cleanliness of food-packing material. Specifically, proposed § 112.116(b) would require that if you reuse food-packing material, you take

measures to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner.

2. Proposed Requirements

Proposed § 112.111 would establish that if you grow, harvest, pack or hold produce that is not covered in this part (*i.e.,* excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to: (a) Keep covered produce separate from excluded produce (proposed § 112.111(a)); and (b) Adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-contact surfaces for covered activities on covered produce (proposed § 112.111(b)). As discussed in the QAR, raw produce may have a variety of microorganisms in and on it, including, occasionally, human pathogens. The types of microorganisms, including human pathogens, detected on raw produce are diverse and may often be found in high numbers (Ref. 204. Ref. 205. Ref. 206). In addition, some human pathogens that are commonly isolated from the growing environment (*e.g., L. monocytogenes*) are reported to adapt and survive in the food production environment (*e.g.,* food contact surfaces, floors, walls, drains, sinks, standing water, and seals) and, thus, pose a potential source of contamination (Ref. 207). The proposed standards included in this part are designed to reduce the likelihood that human pathogens are present in or on covered produce. For this reason, excluded produce that is not grown, harvested, packed and stored in accordance with the standards proposed in this part is likely to present a greater likelihood of contamination with human pathogens than would covered produce that is grown, harvested, packed, and held in accordance with this part. We tentatively conclude that for operations handling both covered and excluded produce, cross-contamination is reasonably likely in the absence of measures directed toward its prevention. Such measures include separation of the two types of produce to avoid physical contact and any transfer of pathogens from one to the other; and cleaning and sanitizing, as necessary, food contact surfaces used on such excluded produce before those surfaces come in contact with covered produce so that any pathogens picked up by the food-contact surface from excluded produce are not transferred to covered produce.

Proposed § 112.112 would require you to take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. For example, you would comply with this provision by not harvesting a head of lettuce if you see evidence of bird excreta on the head of lettuce. As discussed in the QAR, it is well established that animal excreta is a source of pathogens. Transmission of pathogens from animal excreta to covered produce and, subsequently, to humans through consumption is reasonably likely in cases where the presence of animal excreta can be visually confirmed. Therefore, if the presence of animal excreta in a field of covered produce precludes your ability to safely harvest the covered produce, either because a significant portion of the covered produce has animal excreta on it or because the animal excreta that is present would be likely to contaminate food contact surfaces of harvest equipment, you must not harvest the relevant portions of that field.

Proposed § 112.113 would require that you handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards, for example, by avoiding contact of cut surfaces of harvested produce with soil. As discussed in the QAR, research demonstrates that soil microorganisms, including human pathogens, may effectively colonize produce when the produce has lost its protective covering (*e.g.* cuticle) in the course of harvest activities (*e.g.,* cutting or trimming) or when damaged during such operations (Ref. 208. Ref. 209). Once established, the high moisture content of produce provides a suitable environment for survival and growth of such pathogens. Pathogens, if present, may be transferred to cut surfaces of harvested produce from soil and, therefore, preventing unnecessary contact between such cut surfaces and soil will reduce the likelihood of such transfer. For example, you could take steps to temporarily place cut lettuce heads on clean cardboard or other clean surface during field packing, rather than placing them directly on the soil.

We considered washing as a requirement to reduce the likelihood of contamination. Washing is an attractive option because it effectively removes excess dirt, debris, and other organic matter and its use incurs a relatively low cost allowing it to be employed across a variety of equipment (water flumes, hydrocoolers, dips, scrubbers, sorters, etc.) or steps in combination, or in sequence before packaging. Despite these advantages, a number of studies have concluded that wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health significance (Ref. 206. Ref. 210. Ref. 209). Wash water containing an antimicrobial such as chlorine is reported to reduce microbial populations by two or three log units (100 to 1000 fold), but does not eliminate microbes (Ref. 211. Ref. 210). Bacteria may find harborage and protection on plants through hydrophobic areas, stomata, lenticels, punctures, and bruises and where it is not readily washed off (Ref. 212. Ref. 213). Of special significance to bacterial survival on plants are circumstances that lead to bacterial cells being drawn in or internalized inside the edible portion of the plant where they may escape the action of water altogether. This phenomenon, termed internalization, may occur as a consequence of temperature differentials created when warm produce (from field heat or daytime high temperatures) is submerged in cooler water. Under these conditions, infiltration of water occurs because intercellular air spaces within fruits and vegetables contract, thereby creating a partial pressure differential that draws the water into the internal compartments of the plant. If the cooling water contains human pathogens the fresh produce item will now be internally contaminated. This phenomenon has been seen with Salmonella and E. coli O157:H7 in tomatoes, oranges, or mangoes (Ref. 138. Ref. 139. Ref. 214). As part of a post-outbreak study, Penteado *et al.* 2004 reported evidence that Salmonella spp. may have internalized in fresh mangoes during a postharvest cooling step involving a water bath (Ref. 38). We seek comment on whether we should consider washing, alone or in combination with other measures, as a requirement to reduce the likelihood of contamination.

Proposed § 112.114 would prohibit you from distributing covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b) (*i.e.* if it receives commercial processing to

adequately reduce the presence of microorganisms of public health significance). Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground. However, produce that grows off the ground, such as tomatoes and apples, and that drop to the ground before harvest would be considered dropped covered produce. Evidence from studies of tree fruit (*e.g.,* apples and pears) indicates that dropped and damaged fruit contain coliform bacteria in significantly higher numbers than intact tree fruit (Ref. 215). Risk assessment models for apple contamination (Ref. 216) show that dropped apples are more likely to be contaminated with bacteria than tree-picked apples, and dropped fruit used in the production of apple products (*e.g.,* apple cider) are likely to increase rates of product contamination (Ref. 216). While data available to us is primarily derived from studies investigating apples, we tentatively conclude that all dropped covered produce is likely to present a potential likelihood for contamination, although to varying degrees. Studies have indicated that when produce drops to the ground, the produce can become structurally damaged, which is considered to be a factor for proliferation of human pathogens on such produce (Ref. 217. Ref. 218. Ref. 219). Excluding dropped fruit from harvest is also recommended in some existing guidance documents (Ref. 220. Ref. 221. Ref. 44). However, some produce is dropped to the ground as a part of the harvesting practice (*e.g.,* some tree nuts). We expect that such harvesting practices were developed because the fall does not damage the edible crop, because the crop is protected with a durable shell. Accordingly, we have defined ''dropped covered produce'' to exclude produce that is intentionally dropped as part of harvesting. Further, we do not propose to prohibit the use of dropped covered produce in a commercial process (*e.g.,* canning) that is designed to adequately reduce the presence of microorganisms of public health significance. Therefore, dropped covered produce that is exempt under proposed § 112.2(b) may be distributed for such commercial processing as described in proposed § 112.2 (see section V.A. of this document).

We seek comment on this provision and whether specific commodities should be exempted from this provision based on the harvesting practices associated with the commodity and/or the nature of the commodity itself. If specific commodities should be exempted from this provision, please explain the practices, processes, and conditions associated with that commodity that would justify such exemption. We expect that this proposed provision would prevent the marketing for fresh use of produce that may have been bruised as a result of the fall. As noted above, damaged or bruised fruit provide an opportunity for pathogen intrusion into the edible portion and may liberate nutrients for pathogen growth. We note that produce that is intentionally dropped to the ground as part of the harvesting method would not be considered ''dropped covered produce'' as defined in proposed § 112.114 (*i.e.,* produce that drops to the ground before harvest). We seek comment on whether proposed § 112.114 adequately takes into account produce that is intentionally dropped during harvesting and whether such harvesting practices do not cause damage to the produce. Proposed § 112.115 would establish measures that you must take when packaging covered produce. Specifically, proposed § 112.115 would require that you package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin, if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms). The potential for toxin production by *C. botulinum* in mushrooms packaged under reduced oxygen conditions is well-known (Ref. 222). Mushrooms grow close to the ground, which is a source of *C. botulinum* spores. Mushrooms remain metabolically active after harvest, which may quickly reduce the amount of oxygen, particularly when mushrooms are packaged under conditions that limit the transfer of oxygen across the layer of packaging (Ref. 223). In such reduced oxygen or anoxic conditions, *C. botulinum* spores can germinate resulting in the formation of botulinum toxin, which can occur before any overt signs of mushroom spoilage (Ref. 222). Modified or reduced-oxygen packaging of other produce may present a similar risk for botulinum toxin formation (Ref. 224). Perforated packaging film allows free air access to mushrooms and is recommended as a means to reduce the potential for toxin formation in mushrooms (Ref. 225). Other means of preventing toxin formation in modified or reduced oxygen packaging may include use of time-temperature integrators on individual packages of produce to signal when a cumulative time-temperature combination has been reached that presents a risk for *C. botulinum* toxin formation or use of antimicrobial compounds (Ref. 224). We request comment on the need for this proposed provision and on the types or conditions of modified or reduced oxygen packaging methods that may or may not increase the risk of formation of botulinum toxin.

Proposed § 112.116 would establish measures that you must take when using food-packing (including food packaging) material. Specifically, proposed § 112.116(a) would require that food-packing material must be adequate for its intended use. For example, food-packing material that would be adequate for its intended use include plastic bins for holding fresh-picked fruit, wax-impregnated corrugated cardboard for broccoli to be hydrocooled or top-iced after packing, plastic clamshells used for packaging strawberries for retail sale, and single-use cardboard containers for packing tomatoes. Wooden bins or boxes, and canvas bags that may be used during harvest also would need to meet this requirement, and could be used if they are adequately clean and sanitary for their intended use. To implement this provision, you would have to use food-packing materials that are: (1) Cleanable or designed for single use and (2) unlikely to support growth or transfer of bacteria. In addition, proposed § 112.116(b) would require that if you reuse food-packing material, you take measures to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner. Evidence from scientific literature indicates that the number of microorganisms detected on the surface of fruits is directly correlated to the amount of contact time between the fruit commodity and its packing material (Ref. 226. Ref. 227). Although some food-packing material is sufficiently sturdy to be used multiple times, it may serve as a source of contamination in the absence of regular cleaning and sanitizing between each such use. Further, certain food-packing material may have a serviceable shelf life beyond which it may not possible to effectively clean and sanitize the material. It is reasonably likely that such packing material, if it continues to be used, may serve as harborage sites for pathogens, if they become established on its surface.

L. Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation

Proposed subpart L establishes science-based minimum standards that are reasonably necessary to prevent

equipment, tools, buildings, and inadequate sanitation from introducing known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, and to provide reasonable assurances that the covered produce is not adulterated under section 402 of the FD&C Act.

A few comments recommended that equipment used to hold or convey water should be inspected to ensure that it is clean.

We agree that equipment used to hold or convey water should be maintained in a manner necessary to protect against contamination. In 112.42 (b), we would require that you must adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances. In 112.42 (c), we would require that you must adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

1. Comments Relevant to Proposed Provisions

We received some comments in response to the 2010 FR notice that expressed that the use of animals on a farm or their presence near farming operations should not be prohibited.

We address issues related to animals in and around farming operations in subpart I (see section V.I. of this document) of this rule. However, in this subpart, we address the presence of animals in fully-enclosed buildings. Specifically, proposed § 112.127 would require that you take reasonable precautions to prevent domesticated animals, including guard and guide dogs, in and around a fully-enclosed building from contaminating covered produce, food-contact surfaces, and food packing materials with known or reasonably foreseeable hazards.

2. Proposed Requirements

a. Equipment, Tools, and Buildings That Are Subject to the Requirements of This Subpart

Any equipment and tools used during covered activities that are intended to, or likely to, contact covered produce would be subject to proposed subpart L. In addition, instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of undesirable microorganisms or other contamination would be subject to proposed subpart L. In proposed § 112.121, we provide examples of such equipment and tools, *i.e.,* knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport).

Proposed § 112.122 would identify the types of buildings that are subject to the requirements of proposed subpart L. Such buildings would include any fully- or partially-enclosed buildings used for covered activities, including minimal structures that have a roof but do not have any walls (proposed § 112.122(a)). Fully-enclosed buildings are typically used to grow covered produce such as sprouts and mushrooms and may be used to grow a variety of covered produce indoors to create or extend the growing season in a particular geographic area. Partially-enclosed buildings can be used to grow covered produce such as tomatoes, and are often used to pack covered produce. Buildings that are subject to the requirements of the rule would also include storage sheds, buildings, or other structures used to store food-contact surfaces (such as harvest containers and food-packing materials) (proposed § 112.122(b)). We are proposing this requirement because contaminated food-contact surfaces can contaminate covered produce (Ref. 182) (Ref. 228) and, thus, present a potential hazard.

b. General Requirements Applicable to Equipment and Tools

As proposed, § 112.123 establishes general requirements applicable to equipment and tools subject to subpart L. Proposed § 112.123(a) would require you to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. For example, some lettuce coring knives currently used in the industry are designed in a way that gives them the propensity to transfer microbial contaminants from soil to the lettuce (Ref. 229). Using a tool that is designed to minimize the potential for pathogen transfer from soil to the produce and/or that allows for mechanical polishing to facilitate cleaning and sanitizing the tool would enhance food safety (Ref. 230).

Proposed § 112.123(b)(1) would establish that equipment and tools you use must be installed and maintained in a manner that facilitates cleaning of the equipment and of all adjacent spaces. For example, equipment that is permanently installed in an on-farm packing operation would need to be installed in such a manner that both maintenance and cleaning crews are able to easily access any food contact surfaces, protective covering or barriers, and any movable parts or other potential sources of contamination. A conveyor belt system that is part of a grading line would be considered properly installed if there is easy access to the belt (a food-contact surface) for cleaning. The proposed provisions in § 112.123(b)(1) are consistent with the requirements in current § 110.40(a) and § 111.27(a).

Proposed § 112.123(b)(2) would establish that equipment and tools you use must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting or harboring pests. As discussed in the QAR, if farm equipment or tools are stored outside or in a partially-enclosed building, they may attract or harbor pests, which can carry human pathogens (Ref. 231). Appropriate practices for storing and maintaining equipment and tools can reduce the potential for these problems. For example, you would comply with this provision by storing equipment and tools indoors when practical, and when not practical, minimizing surrounding debris and checking periodically for pests.

Proposed § 112.123(c) would establish that seams on food-contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. This provision is consistent with current § 110.40(a) and (b) and § 111.27(a).

Proposed § 112.123(d)(1) would require you to inspect, maintain, and clean and sanitize (when necessary and appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce. This provision is intended to prevent transfer of contaminants on food-contact surfaces of equipment or tools (*e.g.,* harvest knives, grading belts, or harvest

bins) to covered produce. As discussed in the QAR, for example, it has been documented that *E. coli* O157:H7 can be transferred to Iceberg lettuce from contaminated coring devices used in a simulated field coring (Ref. 229). Even food contact surfaces made of stainless steel can transfer pathogens to covered produce, if not properly cleaned and sanitized. For example, transfer of pathogens from stainless steel tools to lettuce has been demonstrated to occur to various extents, depending on the amount of water on the leaf surface (Ref. 232).

Proposed § 112.123(d)(2) would require you to maintain and clean all non-food-contact surfaces of equipment and tools subject to subpart L used in covered activities during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce. The potential for an equipment or tool to come into contact with covered produce varies with the type and intended use of the equipment or tool. Non-food-contact surfaces of tools and equipment used in contact with covered produce can be sources of contamination. Therefore, it is important to maintain such surfaces of covered equipment and tools in a clean and sanitary condition. However, such surfaces may not require cleaning as frequently as those that come into direct contact with produce, and may not require sanitizing. An example of such a surface is the handle of a tool used when working directly with covered produce, although depending on the use, such equipment or tool may be or consist of a food-contact surface. For example, a truck used to harvest produce may not need to be thoroughly cleaned or sanitized; however, the flatbed of the same truck if used to haul un-packed/loose produce would be considered a food-contact surface.

Proposed § 112.123(e) would establish that, if you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards. For example, you may consider the appropriate route for any equipment to move in, through, and out of production fields, and when there may be a need to visually inspect and clean such equipment to prevent contamination or cross-contamination of covered produce. The potential for transfer of contaminants from tractors to covered produce, for example, if the tractors drive through or otherwise come in contact with manure is also highlighted in our GAPs Guide (Ref. 10). We seek comment on the appropriateness of the proposed cleaning provisions related to equipment and tools.

c. General Requirements Applicable to Instruments and Controls

Proposed § 112.124 would establish that instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of pathogens or other contamination, must be: (a) Accurate and precise as necessary and appropriate in keeping with their purpose; (b) adequately maintained; and (c) adequate in number for their designated uses. Proposed § 112.124 is consistent with current § 111.27(a)(6), and similar to requirements in current § 110.40(f). Accuracy addresses whether the recorded measurements are equal to the true value of that which is being measured, while precision addresses whether individual measurements are close to each other when made under the same conditions. Both accuracy and precision are necessary to ensure the validity and reliability of measurements. The appropriate degree of accuracy and precision, however, would need to be determined based on the nature of the instrument and its specific use for the covered activity. Instruments must also be adequately maintained to ensure that they are functioning properly for their intended use. For example, an in-line water oxidation-reduction potential meter that is used to determine the approximate sanitizer concentration in a water flume system must be appropriately maintained to ensure that there is no debris build-up that would interfere with its proper operation. In addition, you must have an adequate number of instruments as needed for the designated use. For example, if you are composting a small pile of manure and monitoring the temperature, one thermometer may be sufficient. However, if you are composting large windrows in excess of several hundred yards in length, and using an automated system to monitor the internal temperature of the pile, you would need multiple thermocouples placed throughout the pile to get a good reading of the overall temperature.

d. Transport of Covered Produce

Proposed § 112.125 would establish that equipment subject to subpart L that you use to transport covered produce during covered activities must be: (a) Adequately clean before use in transporting covered produce; and (b) adequate for use in transporting covered produce. Transport equipment that is intended to, or likely to, contact covered produce that is not clean, or that is not adequate for the covered produce it is being used to transport, can be a source of cross-contamination of covered produce. Equipment used to transport covered produce would not be adequately clean if, for example, there is dirt, filth, organic material, particles of food, remains of previous shipping loads, or any other extraneous materials or contaminants on surfaces that are likely to come into contact with the produce. Equipment used to transport covered produce would not be adequate if, for example, the same equipment is used to haul live animals or garbage that is not completely contained, and the equipment is either not designed in a manner that allows cleaning and sanitizing or it is not cleaned or sanitized, before it is used to transport covered produce. Proposed § 112.125 is consistent with recommendations in FDA's GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 27), and international guidelines (Ref. 96. Ref. 96).

e. Design and Construction Requirements Applicable to Buildings

Proposed § 112.126 would establish requirements applicable to the design and construction of buildings. As proposed, § 112.126(a) requires that your buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or foreseeable hazards. For buildings to be suitable in size, it should have enough room for covered activities to be conducted without cross-contact between covered produce or food-contact surfaces and building materials, non-food-contact surfaces, or clothing. Proposed § 112.126(a)(1) would establish requirements that your building provide sufficient space for placement of equipment and storage of materials. This is necessary for the maintenance of sanitary operations and the conduct of covered activities. The proposed provisions in § 112.126(a)(1) are consistent with requirements in current § 110.20(b)(1) and § 111.20. Proposed § 112.126(a)(2) would establish requirements that your buildings must permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing material with known or reasonably foreseeable hazards. The

potential for contamination must be reduced by effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means. This provision provides flexibility in the precautions you take for your buildings and proposes separation of operations, such as by having sufficient space so that incompatible operations can be kept at a reasonable distance from each other, for example, so that spray coming off equipment being washed does not contact covered produce being packed. The proposed provisions in § 112.126(a) are similar to requirements in current § 110.20(b)(2) and § 111.20.

Proposed § 112.126(a)(3) would require buildings to be constructed in a manner such that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials. Buildings where covered activities occur must be suitably constructed to allow adequate cleaning and sanitizing in order to minimize the presence or persistence of hazards and the potential for damage or contamination of covered produce. Buildings should be kept in good repair so as to prevent drip or condensate from pipes or ceilings to drop onto covered produce or food-contact surfaces, and holes in walls of enclosed buildings from permitting pests access to covered produce or areas of covered activities. The proposed provisions in § 112.126(a)(3) are consistent with requirements in current § 110.20(b)(4) and § 111.20.

Finally, proposed § 112.126(b) would establish requirements that you provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. Standing water can attract pests and support the growth of pathogens, such as *L. monocytogenes,* presenting potential for contamination of covered produce. The proposed provision in § 112.126(b) is similar to requirements in current § 110.37(b)(4) and § 111.15(f)(4).

f. Domesticated Animals in and Around Fully-Enclosed Buildings

Proposed § 112.127(a) would require you to take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by: (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food-contact surfaces, or food-packing material is exposed; or (2) separating domesticated animals in a fully-enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition. As discussed in the QAR, domesticated animals can carry pathogens, potentially resulting in contamination of covered produce or food contact surfaces. However, consistent with current § 110.35(c), we propose to permit guard or guide dogs in some areas of a fully-enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials (proposed § 112.127(b)). You would need to take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing material with hazards from such dogs. We believe that animals such as guard or guide dogs, when kept under control and where the activities of the animal can be contained, are unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials. We seek comment on the appropriateness of this provision and whether proposed provision § 112.127(b) should be extended to all working animals.

g. Pest Control

As discussed in the QAR, pests such as rodents, snakes, lizards, turtles, iguanas, and birds are known to carry human pathogens, such as *Salmonella* spp. and, if not controlled, can cause the contamination of covered produce, food contact surfaces or food-packing materials. Therefore, in proposed § 112.128(a), we propose to require you to take measures reasonably necessary to protect covered produce, food-contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate. Furthermore, we propose to require you to take measures to exclude pests from fully-enclosed buildings (proposed § 112.128(b)) and to prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them, when present) (proposed § 112.128(c)). We recognize that it might be impossible to exclude pests, such as birds, from entering buildings that are not fully-enclosed. To comply with proposed § 112.128(c), you would need to take those steps reasonably necessary to prevent birds or other animals from building nests in partially-enclosed buildings and, if possible, to find and remove any nests that become established. Any measures or steps taken under these provisions would need to comply with applicable wildlife conservation regulations.

h. Toilet and Hand-Washing Facilities

Human feces may contain pathogens in relatively high concentrations (Ref. 233). The most basic measure to prevent the potential transfer of pathogens from human feces into or onto covered produce and food-contact surfaces is to provide toilet facilities that collect and contain human feces. Proposed § 112.129 would establish requirements related to toilet facilities, including that you must provide personnel with adequate, readily accessible toilet facilities, including facilities readily accessible to growing areas during harvesting activities (proposed § 112.129(a)). In proposed § 112.129(b), we propose to establish that toilet facilities must be designed, located, and maintained to: (1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste (proposed § 112.129(b)(1)); (2) be directly accessible for servicing, be serviced and kept clean on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper (proposed § 112.129(b)(2)); and (3) provide for the sanitary disposal of waste and toilet paper (proposed § 112.129(b)(3)). These provisions are intended to contribute to an overall sanitary measure to help protect covered produce and areas where covered activities are conducted from contamination with pathogens. A portable toilet facility that leaks or a fixed toilet facility that lacks proper drainage or backflow devices would not be considered properly designed or maintained. As discussed in the QAR, runoff from such a toilet facility has the potential to directly contaminate covered produce, while contamination of soil and irrigation water from such runoff can have longer-lasting impact. To minimize the potential for contamination during events such as flooding or high winds, toilet facilities should be located away from water sources and water distribution systems, and at a reasonable distance from growing and packing areas. Sewage transport or other servicing trucks should have clear access to toilet facilities to ensure proper collection and disposal of wastes. In addition, workers are more likely to use toilet facilities that are clean, well-stocked, and in good condition (Ref. 234). We recognize that the growing area of a farm may spread

across several acres of land, and workers or visitors may be in growing areas for an extended period of time primarily during harvest activities. At times other than during harvest, we would consider toilet facilities to be readily accessible if, for example, the facility is available to workers at a farm building before and after they work in a growing area, or at a nearby public facility that is readily accessible to your workers. However, during harvest activities we consider it likely that workers and visitors will spend a significant amount of time in growing areas. We point out that the field sanitation requirements prescribed by the Occupational Safety and Health Administration (OSHA) under the Occupational Safety and Health Act, specifically 29 CFR 1928.110, describes the appropriate number of toilets to the number of workers, proper handwashing facilities, maximum worker-to-restroom distance, and frequency of cleaning facilities. Agricultural establishments subject to the requirements of 29 CFR 1928.110(c)(2), must provide one toilet facility for each 20 employees or fraction thereof (except that toilet facilities are not required for employees who perform field work for a period of three hours or less (including transportation time to and from the field) during the day).

As discussed in the QAR, the fecal-oral route for contamination of food with pathogens is well-established and proper washing and drying of hands are fundamental practices demonstrated to be effective in breaking the fecal-oral route of contamination. Therefore, in proposed 112.129(c), we would establish requirements that you provide a hand-washing station during growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, that is in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands. We discuss the importance of hand-washing in presenting the proposed requirements for hygienic practices in section V.D. of this document.

The provisions in proposed § 112.129 are consistent with recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 194), and international guidelines (Ref. 96. Ref. 96). These provisions are also similar to requirements in current § 110.37(d) and § 111.15.

With respect to hand-washing facilities, we propose to require you to provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities (proposed § 112.130(a)). In addition, in proposed § 112.130(b), we would establish requirements that your hand-washing facilities must be furnished with: Soap (or other effective surfactant) (proposed § 112.130(b)(1)); running water that satisfies the requirements of § 112.44(a) for water used to wash hands (proposed § 112.130(b)(2)); and adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service) (proposed § 112.130(b)(3)). As discussed in the QAR, hand-washing is a key control measure in preventing the spread of pathogens from ill or infected workers to covered produce and food-contact surfaces. Workers often touch produce with their bare hands. Hand-washing, when done effectively, can significantly reduce the number of resident bacteria on the hands of a worker who may not be aware of being ill or infected, as well as transient microbial pathogens that get onto hands through contact with the environment or other ill workers. The effectiveness of hand-washing is determined by multiple factors, including whether or not soap is used, the quality of water used, the duration of scrubbing and rinsing, and whether and how hands are dried. The frequency of hand-washing, as well as the efficacy of a single hand-washing event, may also be important factors in the spread of microbial pathogens by ill or contaminated workers (Ref. 107).

Proposed subpart 112.130(c) would establish requirements that you provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards. A hand-washing facility produces waste that can lead to contamination, and such waste needs to be controlled. For example, if the sink of a portable hand-washing station in field actively being harvested does not have a catch-basin or tank, but instead is open the ground, the waste-water from the sink can contaminate the soil. Finally, in proposed § 112.130(d), we would establish that you may not use hand antiseptic/sanitizer as a substitute for soap and water. As discussed in the QAR, hand sanitizers have not been found to be effective substitutes for washing hands with soap and water, because the presence of dirt, grease, or soil reduces their effectiveness in eliminating bacteria. However, we are not proposing to prohibit the use of sanitizers as they may be effective as an additional measure in reducing the number of bacteria on hands after proper washing with soap and water followed by drying

The hand-washing provisions in proposed § 112.130 are consistent with recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), commodity-specific guidances (Ref. 85. Ref. 94. Ref. 194), and international guidelines (Ref. 96). They are also similar to the requirements in current § 110.37(e) and § 111.15(i).

i. Disposal of Sewage, Trash, Litter, and Other Waste

As discussed in the QAR, human feces may contain pathogens in relatively high concentrations and, therefore, sewage must be properly disposed and sewage and septic systems must be maintained to minimize the potential for failure, leakage, or spills (and any leakage or spill appropriately managed) to prevent contamination of covered produce. Events such as flooding or earthquakes also have the potential to damage sewage and septic systems and impair their function and, therefore, it would be appropriate to assess your sewage systems for damage or other failures, following such events. Proposed § 112.131 would establish requirements that apply to the control and disposal of sewage, including that you must dispose of sewage into an adequate sewage or septic system or through other adequate means (proposed § 112.131(a)), which is consistent with current § 110.37(c) and § 111.15(g); you must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards (proposed § 112.131(b)); you must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems (proposed § 112.131(c)); and that after a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure

that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems (proposed § 112.131(d)). These provisions are consistent with recommendations in our GAPs Guide (Ref. 10), commodity-specific guidances (Ref. 44. Ref. 46), and the AFDO Model Code (Ref. 20).

Proposed subpart 112.132 would establish requirements that apply to the control and disposal of trash, litter, and other waste in areas used for covered activities. Proposed § 112.132(a) would establish requirements that you convey, store, and dispose of trash, litter and waste to: (1) Minimize the potential for trash, litter, or waste to attract or harbor pests (proposed § 112.132(a)(1)); and (2) Protect against contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards (proposed § 112.132(a)(2)). In addition, we propose to require that you adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity (proposed § 112.132(b)). The provisions proposed in § 112.132 are consistent with requirements in current §§ 111.15(a) and (g) and similar to requirements in current § 110.37(f). These provisions are also consistent with recommendations for packing areas in our GAPs Guide (Ref. 10), and commodity-specific guidance (Ref. 46).

j. Plumbing

Proposed § 112.133 would establish that plumbing must be of an adequate size and design and be adequately installed and maintained to (1) distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities (proposed § 112.133(a)); (2) properly convey sewage and liquid disposable waste (proposed § 112.133(b)); (3) avoid being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or agricultural water sources (proposed § 112.133(c)); and (4) not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities (proposed § 112.133(d)). An example of a problem that may result from inadequate plumbing is improper drainage of refrigeration drip pans. If drip pans do not drain properly, they may drip onto covered produce or allow moisture to accumulate providing an environment that can support the establishment of and growth of *L. monocytogenes*. Proposed § 112.133 is intended to ensure that your plumbing and water distribution systems do not adversely affect the water you use in covered activities on covered produce. If the plumbing and water distribution systems are not adequately installed and maintained, they may contaminate your water supply and, in turn, contaminate your covered produce through direct contact (such as when you use water in irrigation or harvest activities), or through indirect contact (such as when the contaminated water is used to wash a food-contact surface). Such cross-contamination of clean water and waste water has been implicated in outbreak investigations (Ref. 235). It would also be important to prevent contamination of water that must meet the requirements under subpart E by water that does not meet the relevant requirements. For example, water used for irrigation of covered produce other than sprouts using a direct water application method would need to meet the requirements of §§ 112.41 and 112.44(c) or (d), but would not necessarily meet the requirements of § 112.44(a) (see section V.E. of this document). These provisions are consistent with the requirements in current §§ 110.37(b) and 111.15(f), and with the recommendations in our GAPs Guide (Ref. 10), the AFDO Model Code (Ref. 20), and commodity-specific guidances (Ref. 46. Ref. 44).

k. Control of Animal Excreta and Litter From Domesticated Animals

In proposed § 112.134(a), we would require that, if you have domesticated animals, to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must: (1) Adequately control their excreta and litter, and (2) maintain a system for control of animal excreta and litter. For example, you would comply with this provision by not locating manure piles adjacent to packing sheds in which covered produce is exposed. As discussed in the QAR, pathogens inhabit the gut of a variety of warm-blooded animal species and are often shed in feces in high numbers. If not effectively controlled, such pathogens may persist in the environment for long periods of time (see the QAR) and may pose a threat to water quality from runoff and leaching (Ref. 236. Ref. 169), creating multiple opportunities for these pathogens to contaminate produce or food contact surfaces.

l. Record Keeping

Proposed § 112.140(a) would make clear that records required under this subpart L must be established and kept in accordance with the requirements of subpart O of this part. Records required to be established and kept under this subpart L include documentation of the date and method of cleaning and sanitizing of the equipment you use in growing operations for sprouts (proposed § 112.140(b)(1)) and in covered harvesting, packing, or holding activities (proposed § 112.140(b)(2)). These documentation requirements are intended to enable us to verify and you to ensure that requirements of this subpart are met.

M. Subpart M—Standards Directed to Sprouts

Proposed subpart M would establish science-based minimal standards for the growing, harvesting, packing and holding of sprouts that are reasonably necessary to minimize the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death. As noted in section I of this document, sprouts have been frequently associated with foodborne illness outbreaks (Ref. 3). As a result, we issued our first commodity-specific guidance for sprouts. Likewise, the Codex Alimentarius Commission supplemented its Codex Fresh Fruits and Vegetables Code with a Sprout Annex (Ref. 50).

Sprouts present a special concern with respect to human pathogens than other covered produce because of the warm, moist, and nutrient-rich conditions required to produce sprouts, the same conditions that are also ideal for the proliferation of pathogens if present (Ref. 208. Ref. 16). Therefore, we believe it is necessary to incorporate this additional subpart establishing standards specific to sprouts. The provisions of proposed subpart M are consistent with recommendations in FDA's Sprout Guides (Ref. 14. Ref. 15), industry guidance (Ref. 237), and international regulations and guidelines (Ref. 38. Ref. 191. Ref. 192. Ref. 193).

We are also seeking comment on whether, or to what extent, the measures in this subpart should be applied to soil-grown sprouts. The NACMCF Sprout White paper and our Sprout Guides do not distinguish soil-grown sprouts and hydroponic sprouts (Ref. 14. Ref. 15.

Ref. 16). However, we are not aware of any outbreaks associated with sprouts grown in soil or media, which could be because of the lower percentage of sprouts grown in that manner, the nature of the species of sprouts grown in that manner, or a difference in likelihood of contamination posed by that method and hydroponics. This could be the case because of the relative ease of transfer of pathogens between sprouts in a water environment and, possibly, a greater amplification of pathogens during hydroponic sprout production compared to the more stressful environment for pathogen growth posed by exposure to air and sunlight when seeds are grown under conditions more typical of a natural setting (soil and media methods). On the other hand, we expect that seeds or beans would be a potential vehicle of contamination, regardless of sprouting method employed. Seeds or beans (in the form of seed leaves or cotyledons) could be part of the food consumed, regardless of the method used for sprouting. In addition, flats of soil or media grown sprouts may be placed on a growing rack, similar to hydroponic sprouts grown in clamshells (as opposed to large bins for bean sprouts or rotating drums used to start green sprouts), with overhead sprout irrigation water, providing an opportunity for pathogens, if present, to be spread within a flat of sprouts and to other flats on racks below. Alternatively, flats may be placed side-by-side in a growing area such as a greenhouse, where the likelihood of pathogen spread would presumably be lower than when a growing rack is used.

Finally, as discussed in section IV of this document, while we recommend that farms conduct an operational assessment and develop a food safety plan, at this time, we are not proposing to require them to do so. We request comment on whether, in a final rule, a food safety plan and/or an operational assessment should be required for farms conducting covered activities related to sprouts, either in addition to or in place of the standards proposed in this subpart. We also request comment on whether a written plan similar to the type required under section 418 of the FD&C Act would be more appropriate for farms conducting covered activities related to sprouts.

1. Comments Relevant to the Proposed Provisions

We received very few comments related specifically to sprouts. Those that were submitted were generally supportive of our efforts to create policies to prevent illness and produce safer sprouts, citing the need for addressing residual agricultural chemicals and microbial contamination of seed, seed disinfection treatments, worker health and hygiene, and sanitation. One comment hoped that we understood the realities currently facing the sprout industry worldwide, and would take actions to ensure truly practical measures that would be accepted by the sprout industry, questioning, for example, the need for extensive record keeping or monitoring sprout facilities for *Listeria.* This comment maintained that we should consider current production methods and consumption practices in establishing standards for sprouts.

As discussed further in section V.M.3. of this document, our proposed rule carefully considers the various conditions under which sprouts are grown and consumed. The proposal provides flexibility to achieve the goal of minimizing the risk of known or reasonably foreseeable hazards that are associated with serious adverse health consequences or death. We consider that the proposed requirements for the growing, harvesting, packing and holding of sprouts, as well as for record keeping, are all practical and necessary to protect public health. With respect to consideration of the method of growth, as discussed above, we are seeking comment on whether soil-grown sprouts are subject to the same risk factors as hydroponic sprouts and to whether, or to what extent, the measures in this subpart should be applied to them.

One comment recommended that bean sprouts be subjected to less stringent requirements compared to others, *e.g.,* green sprouts, because bean sprouts are rarely consumed raw (less than 1% according to their estimates). This comment suggested that seed disinfection treatments might not be necessary (or argued for more disinfection method choices) for bean sprouts. Our 1999 Sprout Guides apply to all sprouted seeds and beans (Ref. 14. Ref. 15) and we are proposing in subpart M to cover all sprouts, including bean sprouts. Our earliest efforts to promote sprout safety, including consumer advisories, focused primarily on green sprouts, such as alfalfa and clover sprouts, where we were seeing sprout outbreaks and because we assumed bean sprouts were most often cooked before consumption (Ref. 238). However, in 2002, we updated our consumer advisories to include advice on the risks associated with eating all types of sprouts, including raw and lightly cooked bean sprouts based on four foodborne illness outbreaks associated with mung bean sprouts between 2000 and 2002 (Ref. 239). As noted in section V.A.2.a. of this document, we analyzed consumption of selected produce commodities to determine those that are rarely consumed raw. We included sprouts (alfalfa and mung bean) in our analysis, and based on data available from the NHANES, alfalfa and mung bean sprouts do not meet our criteria for rarely consumed raw commodities (Ref. 79).

2. Proposed Requirements

Proposed § 112.141 would establish measures directed to seeds or beans used to grow sprouts. Seeds and beans used for sprouting are believed to be the vehicle for contamination in most *E. coli* O157:H7 and *Salmonella* foodborne illness outbreaks associated with sprouts (Ref. 3. Ref. 16). Proposed § 112.141 is consistent with our Sprout Guide and other public and private programs (Ref. 50. Ref. 240).

Proposed § 112.141(a) would require that, if you grow seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting. These measures would need to be taken during growing, harvesting, packing, and holding of seeds and beans, which include such activities as cleaning, conditioning, and blending.

Various crops may be grown to produce seeds and beans for sprouting with different production practices, growing seasons, conditions, and crop needs. Some of these plants set seeds or beans without intervention from growers, while others (such as alfalfa) may require steps, such as being cut-back, to encourage seed set. Harvesting, packing, and holding may also vary by seed type and by the conditions needed to maintain seed quality, such as germination. Because of the diversity of practices, processes, and procedures, the controls reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you use for sprouting may vary. Therefore, we are not proposing to prescribe specific measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans. However, you may refer to our recommendations in relevant guidances (Ref. 14. Ref. 10).

It is well-established that sprouts can become contaminated through the use of contaminated seeds for sprouting. Therefore, we considered proposing a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes. Such

a program would provide assurance that seeds or beans received from a third party for use to grow sprouts are grown, harvested, stored, and handled using measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting.

However, a supplier approval and verification program may not be practical or effective for seeds and beans received by sprouters for sprouting purposes. For example, for most crops, only a small percentage of the harvested seeds or beans goes to sprout production (Ref. 16. Ref. 241). Several distributors sell seeds and beans primarily for agricultural use with little or no sales for sprouting (Ref. 16). Seeds and beans have a relatively long shelf-life, sometimes being stored for a year or longer, and they often pass through a number of business entities before their final sale. Therefore, the ultimate end use of seeds and beans will likely not be known by many growers, handlers, or distributors (Ref. 16. Ref. 196. Ref. 192. Ref. 197). We are also not aware of any regulatory standards that include a supplier approval and verification program for seeds and beans received by sprouters for sprouting purposes. For example, Food Standards Australia New Zealand (FSANZ) considered but did not require such a program (Ref. 242). We ask for comment on this approach and whether there are additional practical steps or practices that can be taken to ensure the safety of seeds and beans used for sprout production. Specifically, we request comments on whether a supplier approval and verification program for seeds and beans intended for sprout production is practical and effective.

We also considered whether to propose a requirement that you test incoming seeds and beans, and rejected this approach. Although epidemiological investigations often identify seeds and beans as the most likely source of contamination, contamination may be at very low levels (4 CFU/kg seed) (Ref. 16) and laboratory analyses have frequently been unable to isolate pathogens from implicated seeds or beans (Ref. 243). In a recent EFSA publication, the authors concluded that a 2-class sampling plan ''absence in 25g'', n=5; c=0, as specified in EC Regulation 2073/2005 for sprouted seeds, will not give sufficient confidence to demonstrate the absence of a target pathogen at these low levels in seeds. To increase the probability of rejection of a positive lot, the authors estimated that it would be necessary to analyze kilogram quantities of the sample (Ref. 244). Guidances from Canadian and Irish authorities include recommendations that seeds and beans be tested by the distributor, and that the sprouter obtain a Certificate of Analysis (CoA) for the seeds and beans (Ref. 240. Ref. 245), but recognize the limitations of testing seeds.

While a negative test result is not a guarantee of the absence of pathogens, a positive test result would facilitate detection of contaminated seeds and beans for destroying or diverting to non-food use. Thus, we would encourage seed suppliers and sprouters to test seed using statistically valid sampling and testing protocols. However, we tentatively conclude that testing seeds and beans is not sufficiently reliable to include as a measure necessary to prevent the introduction of known or reasonably foreseeable hazards. Instead, we propose to focus on seed treatment (proposed § 112.142) and testing spent irrigation water from each production batch of sprouts (or testing each production batch of sprouts at the in-process stage when testing spent irrigation water is not practicable) (proposed § 112.143).

When seeds or beans are used to produce sprouts, they are ''food,'' as defined in section 201(f) of the FD&C Act (Ref. 95). The definition of ''food'' in proposed § 112.3 is consistent with this interpretation. When you grow, harvest, pack, and store seeds and beans for sprouting at your operation, you know the end use of the seeds and beans, and proposed § 112.141(a) would require that you exercise control over that input into your sprout production. On the other hand, growers of seeds and beans may be unaware as to whether their crop will be used for sprout production. We seek comment on any provisions that would be effective in reducing the risk posed by contaminated seeds or beans in such cases, without also imposing an undue burden on the agricultural sector that produces seed used primarily for purposes of growing food or feed crops and not intended for use as food for human consumption as sprouts.

Proposed § 112.141(b) through (c) would establish additional requirements to ensure that seeds and beans do not serve as a vehicle for introducing contamination in sprouts. Proposed § 112.141(b) would require that if you know or have reason to believe that a lot of seeds or beans has been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts. Contamination of seeds and beans is generally at a low level and not distributed homogeneously throughout a seed lot. Thus, a seed lot may be in distribution for some time and in use by multiple sprout farms before it is known or suspected to be contaminated. As discussed in the QAR, we are aware of outbreaks associated with multiple sprout farms using the same lot of seed. In addition, pathogens, such as *Salmonella* and *E. coli* O157:H7, can survive for an extended period of time on seeds and beans, as evidenced by outbreaks linked to seed that is a year or two old, so setting aside a potentially contaminated seed lot for later use does not reduce the likelihood of producing contaminated sprouts from that lot of seeds or beans (Ref. 16. Ref. 243). For these reasons, we have tentatively concluded that, once you know or have reason to believe that a lot of seeds or beans is contaminated, through microbial testing or implication as the vehicle in an outbreak, there is reason to believe that other parts of that lot may also be contaminated, you must not use that lot of seeds or beans to produce sprouts. This is consistent with existing guidances and standards (Ref. 16. Ref. 18. Ref. 192. Ref. 193).

Proposed § 112.141(c) would require that you visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards. Visual examination of seeds and beans for sprouting, and the packaging used to ship them, provides an opportunity to see signs of potential contamination, such as rodent or bird feces or urine, which may introduce pathogens into or onto sprouts (Ref. 241. Ref. 246). Feces from rodents and birds are known to carry pathogens (Ref. 247). This proposed provision is consistent with recent FDA and international guidance (Ref. 38. Ref. 18. Ref. 192. Ref. 193).

Proposed § 112.142 would establish measures you must take for growing, harvesting, packing, and holding sprouts. Specifically, proposed § 112.142(a) would require that you grow, harvest, pack, and hold sprouts in a fully-enclosed building. Proposed § 112.142(b) would require that any food-contact surfaces you use to grow, harvest, pack, or hold sprouts must be sanitized after cleaning and before contact with sprouts or seeds or beans used to grow sprouts. As discussed in the QAR, although the source of contamination in outbreaks associated with sprouts has most often been incoming seeds or beans, pathogens can also be introduced during sprout growing, harvesting, packing, and holding.

Therefore, we are proposing these additional requirements for sprout farms (*i.e.,* conducting operations in a fully enclosed building, sanitizing food-

contact surfaces after cleaning) because we have tentatively concluded that the sprouting process represents a unique bacterial amplification step that requires a higher level of care compared to the growing, harvesting, packing, and holding of other covered produce. This proposed approach, a higher level of care compared to produce growing, harvesting, packing and holding generally, is consistent with Codex guidelines (Ref. 50).

Proposed § 112.142(c) would require you to treat seeds or beans that will be used to grow sprouts using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Consistent with our previous discussion of the term ''scientifically valid'' with respect to testing in the proposed rule to establish Current Good Manufacturing Practice requirements for dietary ingredients and dietary supplements (68 FR 12157 at 12198), we use the term ''scientifically valid'' to mean using an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. Methods used for reducing microorganisms of public health significance in seeds or beans for sprouting must be scientifically valid if they are to provide assurance that they are effective.

Prior treatment conducted by a grower, handler, or distributor of seeds or beans, does not eliminate your responsibility to treat seeds or beans immediately before sprouting, at your covered farm. This proposed requirement is consistent with NACMCF recommendations and our Sprout Guide (Ref. 16. Ref. 14) and international guidance (Ref. 193. Ref. 191. Ref. 38). Specifically, NACMCF recommends that seed treatments that deliver less than a 5-log pathogen reduction be coupled with a microbial testing program. We did not cite any specific log reduction in our Sprout Guide as ''adequate to reduce pathogens.'' At that time, few if any seed treatments were thought to be capable of consistently delivering a 5-log pathogen reduction.

A number of treatments have been shown to reduce levels of, but not eliminate, pathogenic bacteria present on seeds. Such treatments are likely to reduce the level of contamination if present and, in turn, decrease the risk for foodborne disease with sprouted seeds (Ref. 16). We cited in the Sprout Guide a 20,000 ppm calcium hypochlorite treatment as an example of a treatment that has been shown to be effective for the reduction of pathogens on seed. Scientific literature indicates that the 20,000 ppm $Ca(OCl)_2$ treatment, widely adopted by sprouters who treat seed prior to sprouting, produces a 2.5 log reduction, with a range of 1.0–6.5 log reduction (Ref. 192. Ref. 201). Other chemical and physical seed disinfection treatments, alone and in combination, have been evaluated for efficacy but there is a high degree of variability in research results based on a number of factors (*e.g.,* seed type, whether seed was naturally or artificially contaminated, level of initial contamination). In their evaluation of the current state of microbiological safety of seeds and sprouts, Fett et al. (Ref. 243) present a comparison of the efficacy of select aqueous chemical disinfection treatments with $Ca(OCl)_2$ for sanitizing alfalfa seed from the literature. Canada recommends a lower level of calcium hypochlorite, 2,000 ppm (Ref. 245).

We acknowledge that several outbreaks have brought into question the effectiveness of seed disinfection treatments. For example, an outbreak of *Salmonella kottbus* in alfalfa sprouts was linked to seed that underwent a chlorine sanitization step, although records indicate the concentration of chlorine was probably lower than the recommended 20,000 ppm (Ref. 248). Conversely, in 1999, an outbreak of *Salmonella enterica* serotype Mbandaka occurred in Oregon, Washington, Idaho, and California. Based on epidemiologic and pulsed-field gel electrophoresis evidence from 87 confirmed cases, the outbreak was linked to contaminated alfalfa seeds grown in California's Imperial Valley. Trace-back and trace-forward investigations identified a single lot of seeds used by five sprout growers during the outbreak period. Cases of salmonellosis were linked with two sprout growers who had not employed chemical disinfection; no cases were linked to the three sprout growers who used seed disinfection (Ref. 249). In another outbreak of *Salmonella typhimurium* in clover sprouts linked to seed sold to multiple sprout operations, sprouters who had treated the seeds in 20,000 ppm chlorine had fewer cases attributed to their sprouts compared to those that did not (Ref. 250). This is consistent with modeling work by Montville and Schaffner, indicating that, while disinfection of seeds prior to sprouting did not guarantee pathogen free sprouts, disinfection reduced the percentage of contaminated batches. Seed disinfection was most effective when contamination was sporadic and at low levels; at a low prevalence (1 out of 10,000 25-g samples are positive), as would normally be expected, the percentage of contaminated batches was reduced from 13.7 to 0.1%. Where the initial contamination was high and uniform, the proportion of contaminated batches was reduced only from 100 to 87.7% (Ref. 251).

For these reasons we continue to believe that seed disinfection treatments are valuable as one of several measures necessary to ensure the safety of sprouts. We ask for comment on this approach.

Proposed § 112.143 would establish requirements for testing procedures you apply to the growing, harvesting, packing, and holding of sprouts. Specifically, proposed § 112.143(a) would require that you test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes* (Lm) in accordance with the requirements of § 112.144. The proposed testing requirement in § 112.143(a) is in response to emerging concerns about positive sample findings and multiple recalls associated with *L. monocytogenes* in sprouts (Ref. 17. Ref. 252). Between 2002 and 2010, there have been 10 recalls involving multiple sprout types due to potential or confirmed contamination with *L. monocytogenes* (Ref. 253). In one of these recalls, the strain found in sprouts matched the strain isolated from 20 confirmed cases of listeriosis in 6 States and positive sample findings from an environmental investigation at the sprouting operation (Ref. 252).

Contamination from *L. monocytogenes* from the environment is common (Ref. 207) and, thus, targeted preventive controls to minimize *L. monocytogenes* in RTE foods are warranted. While appropriate sanitation measures can minimize the presence of environmental pathogens in a sprouting operation, we tentatively conclude that environmental monitoring is still necessary for sprouting operations as an added safety measure. Such monitoring can be conducted by testing for the specific pathogenic microorganism or by testing for an ''indicator organism,'' which can indicate conditions in which the environmental pathogen may be present. Typically, a firm that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. Further steps may be necessary if the indicator organism is

found on retest. Tests for the indicator organism *Listeria* spp. detect multiple species of *Listeria,* including the pathogen *L. monocytogenes.* For example, USDA's FSIS regulations and guidelines use *Listeria* spp. as an appropriate indicator organism for *L. monocytogenes* in for RTE meat or poultry products exposed to the processing environment after cooking to prevent product adulteration by *L. monocytogenes* (Ref. 254). FDA's current thinking is that *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes,* and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for *Listeria* spp., have public health benefits. The taking of actions based on the presence of an appropriate indicator organism is protective of public health, since there will be times when steps are taken in the absence of the pathogen. Therefore, we tentatively conclude that testing the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* is a necessary measure to ensure the safety of sprouts.

Proposed § 112.143(b) would require that you either: (1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* spp. in accordance with the requirements of § 112.146; or (2) if testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts), that you test each production batch of sprouts at the in-process stage (*i.e.,* while sprouts are still growing) for *E. coli* O157:H7 and *Salmonella* spp. in accordance with the requirements of § 112.146. A production batch for which either of these pathogens is detected in the spent irrigation water for the sprouts would be considered adulterated under Section 402(a)(4) of the FD&C Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. A production batch for which either of these pathogens is detected in the sprouts would be considered adulterated under Sections 402(a)(1) of the FD&C Act, in that the sprouts contain a poisonous or deleterious substance which may render it injurious to health. Therefore, we tentatively conclude that microbiological testing of spent irrigation water from each production lot (or of each production batch of sprouts) is necessary to provide reasonable assurances that sprouts are not adulterated under Section 402 of the FD&C Act. The proposed testing requirement in § 112.143(b) to test spent sprout irrigation water (or sprouts) for *Salmonella* and *E. coli* O157:H7 would codify current recommendations in our Sprout Guides and is consistent with existing international guidelines and regulations (Ref. 38. Ref. 191. Ref. 193).

We are proposing these testing requirements in § 112.143(b) in addition to the proposed treatment requirements in § 112.142(c) because pathogens that are merely injured, but not killed, by seed treatment could potentially grow out again when subjected to enrichment conditions, as experienced during sprouting (Ref. 16. Ref. 74). Because seed disinfection treatments can reduce, but may not eliminate, pathogens on seed, we are proposing to require microbiological testing. Spent irrigation water that has flowed over and through sprouts is a good indicator of the types and quantities of microorganisms in the sprouts themselves (differing by only 1 log or less from the level in the sprouts) and the microflora in spent irrigation water is fairly homogeneous (Ref. 15. Ref. 198. Ref. 209). The optimal time for testing is when pathogen levels are highest (approximately 24–48 hours after the start of sprouting), but also when it is early enough in the sprouting process to obtain results before product is shipped.

We have emphasized testing irrigation water in proposed § 112.143(b) because testing sprouts has several significant disadvantages compared to testing spent irrigation water. First, contamination of sprouts is not likely to be as homogeneous as is the spent irrigation water (Ref. 243. Ref. 255). Second, multiple sprout samples must be taken from different locations in the drum or trays to ensure that the sample collected is representative of the batch. Furthermore, additional preparation (*e.g.,* selecting representative subsamples for analyses, blending or stomaching) is required when testing sprouts. Each additional step introduces a possibility for error. Consequently, testing of spent sprout irrigation water is generally preferred over testing sprouts unless production methods make it impractical to test spent sprout irrigation water. For example, spent irrigation water may not be available when sprouts are grown in soil.

We chose pathogen testing for *Salmonella* spp. and *E. coli* O157:H7 because these pathogens are the two most common agents in sprout-associated outbreaks in the U.S. (Ref. 3). Recently, EFSA concluded that there are currently no indicator organisms that can effectively substitute for the testing of pathogens in seeds, sprouted seeds or irrigation water (Ref. 244). We tentatively concur with this conclusion.

In developing our Sprout Guides in 1999 and in deliberations for this proposed rule, we also considered whether to include testing spent sprout irrigation water for *L. monocytogenes,* in addition to testing it for *Salmonella* spp. and *E. coli* O157:H7. However, we tentatively concluded that testing spent sprout irrigation water for *Listeria* has a number of potential challenges. The warm, moist, nutrient-rich conditions during sprouting encourage the proliferation of *Salmonella* and *E. coli* O157:H7 and this proliferation increases the probability of their detection, if present. In contrast, *Listeria* may be a poor competitor at the warmer temperatures and against the high level of native microflora present during the sprouting process. In addition, *Listeria* is ubiquitous. We would expect frequent positives using rapid tests for *Listeria* spp., which would not necessarily mean pathogens were present. Such testing would need to be followed by confirmatory testing to determine whether or not *L. monocytogenes* was present in order to determine appropriate actions with respect to the product. While rapid test kits are now available to screen for *L. monocytogenes,* their use on spent sprout irrigation water or sprouts would need to be validated (Ref. 14). We tentatively conclude that environmental monitoring for *Listeria* spp. or *L. monocytogenes* is the most practical approach for control of this pathogen. We request comments on this tentative conclusion.

We also considered the appropriateness of proposing provisions for testing spent sprout irrigation water for non *E. coli* O157:H7 shiga toxin-producing *E. coli* (STEC) which were involved in the recent large sprout associated *E. coli* O104 foodborne illness outbreak in Europe (Ref EU OB). The O104:H4 strain that caused the outbreak in Europe was an unusual strain that none of the tests that were being used to test for enterohaemorrhagic *E. coli* (EHEC) at that time would have picked it up. The challenge is that there are estimated to be 400 serotypes of *E. coli* that produces any one of the 3 Stx1 and/or 8 Stx2 subtypes and many of these are isolated from environmental and animal sources but have not been implicated in human illness. Many of the STEC strains entailed tedious plating and retesting to isolate and even longer to serotype (Ref. 256). For these reasons, we tentatively conclude that proposing to require testing spent sprout irrigation water for

non *E. coli* O157:H7 STECs would not be a practical approach at this time.

We request comments on this tentative conclusion, and on whether pathogens in addition to *E. coli* O157:H7 and *Salmonella* spp. should be included in testing of spent sprout irrigation water or in-process sprouts, either by specifically listing the additional pathogens or by set criteria (*e.g.,* association with one or more outbreaks linked to sprouts) for inclusion.

Proposed § 112.144 would establish requirements for how you test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes.* Specifically, proposed § 112.144(a) would require that you establish and implement a written environmental monitoring plan that is designed to find *L. monocytogenes* if it is present in the growing, harvesting, packing or holding environment. Proposed § 112.144(b) would require that your written environmental monitoring plan be directed to sampling and testing for *Listeria* spp. or *L. monocytogenes.* Proposed § 112.144(c)(1) through (3) would require that your written environmental monitoring plan include a sampling plan that specifies: What you will test collected samples for (*i.e., Listeria* spp. or *L. monocytogenes*) (proposed § 112.144(c)(1)); How often you will collect environmental samples, which must be no less than monthly (proposed § 112.144(c)(2)); and Sample collection sites. The number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment (proposed § 112.144(c)(3)). Proposed § 112.144(d) would require you to collect environmental samples and test them for *Listeria* spp. or *L. monocytogenes* according to the method in § 112.152.

Proposed § 112.144(c)(1) would require that you specify whether you will be testing for the pathogen *L. monocytogenes* or the indicator organism, *Listeria* spp. As discussed above, FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes.* FDA expects environmental monitoring to be conducted with sufficient frequency to detect the environmental pathogen or appropriate indicator organism if present. We tentatively conclude that monthly sampling and testing is a minimum requirement (proposed § 112.144(c)(2)). More frequent testing may be needed. For example, the frequency of monitoring for environmental pathogens should increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased likelihood of contamination, *e.g.,* construction (Ref. 211. Ref. 212). The frequency of taking environmental samples will vary depending on existing data on the presence of the environmental pathogen of concern in the environment where foods are exposed to the environment. In the absence of information, data should be generated to assist in determining the frequency of monitoring (Ref. 257). We request comment on whether the minimum frequency of at least monthly for environmental monitoring is adequate to assess whether the measures taken to minimize the risk associated with *L. monocytogenes* in sprouts are effective. We tentatively conclude that specifying the frequency of testing in the written environmental monitoring plan is necessary to enable assurance by the operator and verification by FDA that testing efforts are consistent with a carefully thought through effort to find the environmental pathogen if it is present in the environment.

The purpose of environmental monitoring is to verify the implementation and effectiveness of sanitation measures for controlling the presence of *L. monocytogenes* in the sprout production environment. The monitoring must be designed to find environmental pathogens that remain in the sprouting operation after routine cleaning and sanitizing procedures in order to prevent contamination of product that could lead to illness. To accomplish this purpose, there must be a scientific basis for the locations selected for sampling, the number of samples taken, the frequency of sampling, the sampling procedures used and the test methodology. The sampling must be biased—*i.e.,* the locations to be tested must be those in which the environmental pathogens can enter the environment where the food is exposed and those areas where harborage of the pathogen is likely (Ref. 258).

One approach to defining sampling locations is to divide the sprouting operation into zones based on the likelihood of contamination of the product. A common industry practice is to use four zones (Ref. 213. Ref. 212): Zone 1 consists of food-contact surfaces; Zone 2 consists of non-food-contact surfaces in close proximity to food and food-contact surfaces; Zone 3 consists of more remote non-food-contact surfaces that are in the area used for growing, harvesting, packing, and holding and could lead to contamination of zones 1 and 2; and Zone 4 consists of non-food-contact surfaces, outside of the area used for growing, harvesting, packing, and holding from which environmental pathogens can be introduced into the growing, harvesting, packing, and holding environment. Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater likelihood of food contamination if the environmental pathogen is present in these zones. Information on appropriate locations for sampling within these zones can be found in the literature (Ref. 175. Ref. 212). Operators should become familiar with locations in which environmental pathogens have been found in other sprout firms and use this information in selecting sites to sample.

L. monocytogenes frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. *L. monocytogenes* organisms work their way out of the harborage site during production and contaminate food. Testing food-contact surfaces for *Listeria* spp. is a commonly recommended verification measure for firms producing refrigerated RTE foods (Ref. 175. Ref. 211).

Examples of appropriate non-food-contact surfaces that could be monitored include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, and motor housings. Standing water in growing, harvesting, and packing areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for *L. monocytogenes* or *Listeria* spp. is a commonly recommended verification measure for firms producing refrigerated or frozen RTE foods (Ref. 258. Ref. 259) and can detect *L. monocytogenes* that is brought into the plant by people or objects. Actions you then take can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination.

Proposed § 112.145 would establish requirements for actions you must take if you detect *Listeria* spp. or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, *i.e.,* Conduct additional microbial testing of surfaces and areas surrounding the area where *Listeria* spp.

or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* spp. or *L. monocytogenes* to have become established in a niche (proposed § 112.145(a); Clean and sanitize the affected surfaces and surrounding areas (proposed § 112.145(b)); Conduct additional microbial sampling and testing to determine whether the *Listeria* spp. or *L. monocytogenes* has been eliminated (proposed § 112.145(c)); Conduct finished product testing when appropriate (proposed § 112.145(d)); and Perform any other actions necessary to prevent reoccurrence of the problem (proposed § 112.145(e)). Testing the environment of a sprouting operation for *L. monocytogenes* (or for *Listeria* spp. as an indicator of potential contamination with *L. monocytogenes*), and taking actions to eliminate *L. monocytogenes* or *Listeria* spp. when found in the environment of a sprouting operation, is an important component of controlling microorganisms of public health significance (Ref. 175. Ref. 211). The actions we are proposing to require, including additional testing to determine the extent of contamination, ensuring contamination is eliminated and taking steps to prevent its recurrence, are consistent with recommendations in our *Listeria* Guide (Ref. 260).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, steps must be taken to eliminate the organism, including finding a harborage site if one exists (Ref. 175. Ref. 211) (Ref. 257). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Actions must be taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Sampling and microbial testing from surfaces surrounding the area where the test organism was found (proposed § 112.145(a)) are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas (proposed § 112.145(b)) are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing (proposed § 112.145(c)) are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. 207). The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. 259). However, finding the test organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Ref. 257).

Proposed § 112.145 would not specify how certain actions must be performed, such as the number of sites to test when the test organism is found in a sprouting operation, or how to clean and sanitize the surfaces on which the test organism was detected. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures will depend on the sprouting operation and the equipment. We tentatively conclude that, when microbial testing is conducted as part of steps in light of the results of environmental monitoring, specifying such procedural requirements would not provide facilities with sufficient flexibility to develop and implement aggressive and appropriate actions to find and eliminate the source of the contamination in the environment. Such actions may involve investigative procedures when the initial measures have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or produce at multiple times during the day while the equipment is operating and producing product (Ref. 207).

Proposed § 112.145(d) would require that if environmental monitoring identifies the presence of an environmental pathogen or indicator organism, the operator conduct finished product testing, when appropriate. As discussed in section IV.I. of this document, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If you detect an environmental pathogen on a food-contact surface, the sprouting operation should presume that the produce is adulterated under Section 402(a)(4) of the FD&C Act.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The potential for food to be contaminated directly from contamination in or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment.

Proposed § 112.145(e) would require that if environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the operator perform any other steps necessary to prevent recurrence of the contamination. Actions taken as a result of monitoring for an environmental pathogen or an indicator organism for such pathogen must ensure these requirements are met. The measures for environmental monitoring specified in proposed § 112.145(a) through (d) are not all inclusive. Examples of measures that may be necessary include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (*e.g.,* hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. 180. Ref. 219). Additional information on measures for environmental monitoring can be found in the literature (Ref. 180. Ref. 221. Ref. 219). Proposed § 112.145 is consistent with the FSIS *Listeria* Guidelines (Ref. 254).

Proposed § 112.146 would establish requirements for how you collect and test samples of spent sprout irrigation water or sprouts. Specifically, proposed § 112.146(a) would require that you establish and implement a written

sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination. Additionally, proposed § 112.146(b) would require that, in accordance with the written sampling plan required under paragraph (a) of this section, you aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for *E. coli* O157:H7 and *Salmonella* spp. using a method that has been validated for its intended use (testing spent sprout irrigation water or sprouts) to ensure that the testing is accurate, precise, and sensitive in detecting these pathogens. This proposed provision is consistent with recommendations in our Sprout Testing Guide, the Canada and Irish Codes and the FSANZ standard (Ref. 15. Ref. 206. Ref. 201. Ref. 203).

One means to test for *E. coli* O157:H7 and *Salmonella* spp. as required under proposed § 112.146(b) is to follow our guidance on sampling and testing spent irrigation water or sprouts (Ref. 15). The methods described in our guidance have been validated to be effective on spent sprout irrigation water and sprouts (Ref. 15. Ref. 223. Ref. 224). The effectiveness of detection methods can vary depending on multiple factors, including but not limited to whether the sample tested is representative of the food, type of food, level of microflora present, the enrichment procedure and type of test used. Spent sprout irrigation water and sprouts have a high level of natural microflora that can interfere with detection (Ref. 15. Ref. 243). Therefore, other methods that have been validated to be effective for other foods may not work for spent sprout irrigation water and sprouts. Because the microflora in spent sprout irrigation water is more homogeneous compared to seeds or sprouts, sampling procedures described in our guidance for sprout irrigation water are relatively simple. In addition, spent sprout irrigation water can be used directly in the test procedures described in our guidance, thus reducing the possibility of error (Ref. 15. Ref. 243). Sampling spent sprout irrigation water or sprouts is an important testing procedure to ensure contaminated product does not enter commerce. The testing procedures described in our guidance give accurate results as quickly and simply as possible on the presence or absence of *E. coli* O157:H7 and *Salmonella* spp.

Proposed § 112.150 would establish requirements for records that you must establish and keep regarding sprouts. Under proposed § 112.150(a), you must establish and keep the required records in accordance with the requirements of proposed subpart O. As discussed in section V.O. of this document, proposed subpart O would establish general requirements applicable to all records.

Proposed § 112.150(b) would require you to establish and keep the following records: Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm (proposed § 112.150(b)(1)); your written environmental monitoring plan in accordance with the requirements of § 112.144 (proposed § 112.150(b)(2)); your written sampling and testing plan for each production batch of sprouts in accordance with the requirements of § 112.146(a) (proposed § 112.150(b)(3)); the results of any testing conducted in accordance with the requirements of §§ 112.143 and 112.144 (proposed § 112.150(b)(4)); any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152 (proposed § 112.150(b)(5)); and the testing method you use in accordance with the requirements of § 112.146(b) (proposed § 112.150(b)(6)). We are proposing to require you to keep the above records specific to sprout operations in order to help document your compliance with the provisions of this rule. We tentatively conclude that such records are needed for us to verify and you to ensure that appropriate measures are being followed consistently and correctly (*e.g.,* your sampling plan for spent sprout irrigation water from each production lot). The records would also allow FDA or you to identify trends that might signal a need to adjust the measures in your environmental monitoring plan to improve its effectiveness and reliability (*e.g.,* test results from your environmental monitoring program may signal the need to enhance sprouting operation cleaning and sanitation).

N. Subpart N—Analytical Methods

Proposed subpart N would specify methods of analysis for testing the quality of water and the growing environment for sprouts, as required under proposed subparts E and M (see sections V.E. and V.M., respectively, of this document).

Proposed § 112.151 would establish that you must test the quality of water to satisfy the requirements of § 112.45 by one of three methods: (1) Official methods of analysis published by the AOAC International; (2) standards methods for the examination of water and wastewater as published by the American Public Health Association; or (3) methods prescribed in the FDA Bacteriological Analytical Manual, or by another method that is at least equivalent to the above-mentioned three methods in accuracy, precision and sensitivity in detecting *E. coli.*

Proposed § 112.151(a)(1) provides for the use of official methods of analysis published by AOAC International in the latest edition of their publication ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 18th edition, revision 4 (published in 2011). The Official Methods of Analysis of AOAC International (18th Ed., revision 4, 2011) would be incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 5.

Proposed § 112.151(a)(2) would establish that methods of analysis published in the Standard Methods for the Examination of Water and Wastewater (21st Edition, 2005), American Public Health Association would be acceptable for testing the quality of water. In addition, the Standards Methods for the Examination of Water and Wastewater, (21st Ed., 2005), would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5.

Proposed § 112.151(a)(3) would establish that methods of analysis published in Chapter 4 of the FDA Bacteriological Analytical Manual (Edition 8, Revision A, 1998) (BAM), as updated in June 2011, would be acceptable for testing the quality of water. In addition, Chapter 4 of the BAM (Edition 8, Revision A, 1998), as updated in June 2011, would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. With advances in science and as appropriate, FDA periodically updates the BAM to add newer methods or revise existing ones. For the purposes of this proposed rule, we refer to Chapter 4 of the BAM (edition 8, revision A, published in 1988) as updated in June 2011. However, should FDA update or revise the methods and procedures currently listed in Chapter 4 of the June 2011 version, for the purpose of testing the quality of water, we encourage industry to use such relevant, updated methods and procedures.

Proposed § 112.151(a)(4) would provide for the use of a method that is at least equivalent in accuracy, precision, and sensitivity to the methods in § 112.151(a)(1), (a)(2) or (a)(3). Test kit methods are generally not published in the literature due to their proprietary nature. FDA is aware of

programs, such as the AOAC Research Institute's Performance Tested Methods Program that provides an independent third-party review of proprietary test method performance. Test methods demonstrated to meet acceptable performance criteria are granted Performance Test Methods (PTM) status. The PTM certification assures users that an independent assessment has found that the test method performance meets an appropriate standard for the claimed use. FDA would consider methods, particularly test kit methods, approved by the PTM program or other similar programs acceptable for testing the quality of water. FDA is also aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems for pathogens and water quality. Many of these products undergo rigorous internal quality control and performance testing, as well as receive additional third-party and/or regulatory approvals. FDA is also aware that the Environmental Protection Agency (EPA) approves analytical methods that industrial and municipal facilities use to determine pollutants of wastewater (published in 40 CFR Part 136) and to meet federal requirements or to demonstrate compliance with drinking water and ground water regulations (40 CFR 141.402 and 40 CFR 141.403). For example, the EPA, has approved the use of E*Colite® Test, m-ColiBlue 24® Test, and Colitag® Test for compliance monitoring related to EPA's Ground Water Rule. FDA would consider these tests acceptable for testing the quality of water to satisfy the requirements of § 112.45.

Proposed § 112.152 establishes the methods you must use to test the growing environment for *Listeria* spp. or *L. monocytogenes* to satisfy the requirements of §§ 112.143(a) and 112.144. As proposed, you must test environmental samples using the methods and procedures described in Chapter 10 of the BAM, ''*Listeria monocytogenes,* Detection and Enumeration of *Listeria monocytogenes* in Foods.'' Chapter 10 of the BAM (Edition 8, Revision A, 1998), as updated in April 2011, would be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. With advances in science and as appropriate, FDA periodically updates the BAM to add newer methods or revise existing ones. For the purposes of this proposed rule, we refer to Chapter 10 of the BAM (Edition 8, revision A, published in 1998) as updated in April 2011. However, should FDA update or revise the methods and procedures currently listed in Chapter 10 of the April 2011 version, for the purpose of testing the growing environment for *Listeria* spp. or *L. monocytogenes,* we encourage industry to use such relevant, updated methods and procedures.

Proposed § 112.152 would also provide for the use of a method at least equivalent in accuracy, precision, and sensitivity in detecting *Listeria* spp. or *L. monocytogenes* as is the method described in Chapter 10 of the BAM. For example, prescribed rapid detection kits with their respective enrichment media may be conditionally used to screen for presence of *Listeria* contaminants. Isolates may be rapidly positively or negatively confirmed as *L. monocytogenes* by using specific test kits. FDA is aware that there are numerous scientific testing and diagnostic development companies that have invented rapid tests and systems for *Listeria* spp. or *L. monocytogenes.* Many of these products undergo rigorous internal quality control and performance testing, as well as receive additional third-party and/or regulatory approvals. As discussed above in proposed § 112.151(a)(4), FDA would consider methods, particularly test kit methods, approved for example by the AOAC Research Institute's Performance Tested Methods Program PTM program or other similar, acceptable for testing *Listeria* spp. or *L. monocytogenes.*

O. Subpart O—Requirements Applying to Records That You Must Establish and Keep

As proposed, subpart O discusses the general requirements applicable to documentation and records that you must establish and maintain under proposed part 112.

1. Comments Relevant to the Proposed Requirements

We received several comments in response to the 2010 FR notice that addressed issues relevant to establishing and maintaining documents and records. Comments expressed concern over the costs of complying with record keeping requirements. Several comments also stated that there should not be a requirement for electronic record keeping for farmers, especially if they are small-scale. One comment requested that, to protect the confidentiality of individual farm businesses, any recordkeeping requirements be accompanied by assurance that information accessed by federal government authorities with respect to food safety protocols will remain confidential. Another comment requested that we consider pre-existing records kept by the produce industry for other purposes, so as to avoid duplication, while another farmer commented that records or documents would not ensure safety and, therefore, asked that records should be required for only annual activities, such as employee training and surveys of surrounding land activities. Finally, several comments indicated that the current legal liability system in the United States serves to discourage any grower or packing house from keeping additional detailed records related to food safety and that such records are subject to intrusive judicial subpoena power.

We believe that documentation of some practices is critical to ensure that science-based minimum produce safety standards proposed in this rule are adequately implemented on the farm. Records are useful for keeping track of detailed information over a period of time. Records can identify patterns of problems and, thus, enable a farm to find and correct the source of problems. Records are also useful for investigators during inspections to determine compliance with requirements (*e.g.,* by FDA investigators to determine compliance with requirements that would be established by this rule, or by a third party auditor that a farm or retailer may voluntarily engage under a business arrangement between the farm and the retailer). Therefore, we tentatively conclude that records of only annual activities are insufficient to ensure produce safety. However, in determining those circumstances in which records are necessary as part of science-based minimum standards that minimize the risk of serious adverse health consequences or death and provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act, we considered the statutory direction in section 419(c)(1)(C) of the FD&C Act to comply with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) ''with special attention to minimizing'' the recordkeeping burden on the business and collection of information as defined in that act. We propose to require records in instances where maintenance of detailed information is needed to keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards, where identification of a pattern of problems is important to minimizing the risk of such hazards, or where they are important to facilitate verification and compliance with standards and this cannot be effectively done by means other than a review of records. See section IV.E of this document for further discussion.

We appreciate the concerns expressed by some commenters with respect to cost and burden to farms. To the extent possible, we attempted to propose documentation requirements that are risk-based and capable of being tailored to your individual farm, taking into account the unique characteristics of the operation, the commodities handled, and the operation's growing, harvesting, packing, and holding procedures. A large majority of growers, farmers, and producers indicated during listening sessions and other stakeholder discussions that they already practice good agricultural practices and keep adequate records. They agreed that such recordkeeping is necessary. Moreover, they indicated that the cost of a large scale recall event would have the potential to far exceed the cost of routine record keeping.

As proposed, the recordkeeping requirements allow the use of existing records and do not require duplication, provided such records satisfy all of the applicable requirements of this part (see proposed § 112.163). In addition, per proposed § 112.165, electronic records would be acceptable but would not be required by this subpart. Records would be acceptable under this subpart if kept in forms as diverse as hard copies of handwritten logs, invoices, and documents reporting laboratory results, provided that they are indelible and legible.

We understand the concerns regarding confidentiality. Our disclosure of information is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under part 20, which include protection for confidential commercial information and trade secrets. We note that many segments of the food industry already are subject to food safety-related recordkeeping requirements similar to those proposed in this subpart. Other existing food safety regulations, such as the infant formula quality control procedures regulation (§ 106.100), the dietary supplement regulation (§ 111.605 and § 111.610), the acidified foods regulation (§ 114.100), the regulation on production, storage, and transportation of shell eggs (§ 118.10), the juice HACCP regulation (§ 120.12), and the seafood HACCP regulation (§ 123.9) require similar record keeping. In addition, many farmers that are part of the various programs such as National Organic Program and LGMA already have similar recordkeeping requirements (Ref. 45. Ref. 261). Recordkeeping has proven useful for the above-mentioned food industries and, thus far, we are not aware that any of these industries has been adversely affected by excessive judicial subpoenas resulting from their recordkeeping.

2. Proposed Requirements

Proposed subpart O would establish requirements that would be applicable to all records required by part 112. FDA tentatively concludes that the requirements in subpart O describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts would aid farms in complying with the requirements of part 112; and allow farms to show, and FDA to determine, compliance with the requirements of part 112.

a. General Requirements

As proposed, § 112.161(a)(1) requires that your records include: (i) The name and location of your farm; (ii) actual values and observations obtained during monitoring; (iii) an adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record; (iv) the location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and (v) the date and time of the activity documented.

The name and location of your farm and the date and time would allow the owner, operator, or agent in charge of a farm (and, during inspection, an FDA investigator) to assess whether the record is current and establish the relevance of the record to your farm, which is necessary for review by regulators. An adequate description of covered produce would allow the farm to more readily track measures, identify a pattern of problems, and verify compliance. Such a description will also allow the farm to identify specific produce for which the standards of this part have not been met, and to take appropriate measures as provided for under § 112.11.

Recording actual values and observations during monitoring are necessary to produce an accurate record. Notations that monitoring measurements are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and observations (*e.g.,* temperatures and turnings in treating biological soil amendments of animal origin) are vague and subject to varying interpretations and, thus, will not ensure that required measures have been taken or standards have been met. In addition, it is not possible to discern a trend without actual measurement values.

Proposed § 112.161(a)(1) is consistent with our HACCP regulations for seafood and juice. Our HACCP regulations for seafood and juice require that all records include the name and location of the processor; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation; and where appropriate, the identity of the product and the production code, if any (§§ 123.9(a) and 120.12(b), respectively). Our HACCP regulations for seafood and juice also require that records contain the actual values (such as temperature) and observations obtained during monitoring (§§ 123.6(c)(7) and 120.12(b)(4), respectively).

Additional requirements in proposed § 112.161(a) include that records must be created at the time an activity is performed or observed (proposed § 112.161(a)(2)); be accurate, legible, and indelible (proposed § 112.161(a)(3)); and be dated, and signed or initialed by the person who performed the activity documented (proposed § 112.161(a)(4)).

These requirements would ensure that the records are useful to the owner, operator, or agent in charge of a farm in complying with the requirements of part 112, for example, in documenting compliance with monitoring requirements. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of part 112. For example, the signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. These proposed requirements are consistent with our HACCP regulations for seafood and juice. Our HACCP regulations for seafood and juice require that processing and other information be entered on records at the time that it is observed (§§ 123.9(a)(4) and 120.12(b)(4), respectively).

As proposed, under § 112.161(b), when records are required to be established and kept in subparts C, E, F, L, and M of this part (§§ 112.30, 112.50, 112.60, 112.140, and 112.150), you must establish and keep documentation of actions you take when a standard in those subparts is not met. This documentation is necessary to show that you have taken the steps reasonably

necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. For example, if under § 112.44(b) you are required to discontinue the use of agricultural water and take corrective steps, this provision would require you to establish and keep a record of the corrective steps that you took.

As proposed, § 112.161(c) would require a supervisor or responsible party to review, date, and sign those records that are required under 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b). These records relate to certain of your testing, monitoring, sanitizing, and corrective action activities. As described above, one of the primary purposes for establishing and maintaining records is so that you can review the records to see if the requirements of this part have been met. Requiring a signature from a supervisor or responsible party for these records emphasizes the importance of such a review.

b. Storage of Records

Proposed § 112.162 would establish the requirements regarding where your records must be stored. Proposed § 112.162(a) establishes that offsite storage of records is permitted after 6 months following the date the record was made if such record can be retrieved and provided onsite within 24 hours of request for official review. FDA realizes that the proposed requirements for recordkeeping could require some farms to store a significant quantity of records, and that there may not be adequate storage space in the farm for these records. Providing for offsite storage of most records after 6 months would enable a farm to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available. Proposed § 112.162(b) would clarify that electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm. For example, we would consider electronic records to be onsite if they were available from your computer, including records transmitted to your computer via a network connection or accessed from either the Internet or electronic or digital storage applications.

Proposed § 112.162 is consistent with our HACCP regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (§ 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review and considers electronic records to be onsite if they are accessible from an onsite location (§ 120.12(d)(2)). We seek comment on the appropriateness of the proposed recordkeeping requirements.

c. Use of Existing Records

As proposed, § 112.163 would clarify that the regulations in this part do not require duplication of existing records if those records contain all of the information required by this part. In this provision, we seek to minimize the burden of keeping records to that which is necessary to accomplish the intended purposes of this part.

For example, as proposed, you are not required to duplicate existing records, such as records kept to satisfy the requirements of the National Organic Program, if those records contain all of the information required by this part. Additionally, you are not required to keep all of the information required by this part in one set of records. Similarly, if you have records containing some but not all of the required information, this proposed regulation provides you the flexibility to keep any additional information required by this part either separately or combined with your existing records. While we propose this provision to give you the greatest degree of flexibility, we remind you that keeping records together in one place likely will expedite review of records in the event of a public health emergency or during an FDA inspection or investigation.

d. Length of Time for Records Storage

Proposed § 112.164(a) would require that you keep records required by this part for two years after the date the record was created. Retaining records for at least this length of time is necessary to ensure that the records are available for reference during verification activities as well as during FDA inspections. It is also critical for documentation and observation of trends of the food safety risks that may affect your operation over time. Multi-year retention of records allows an owner, operator, or agency to better understand and proactively respond to the risk factors affecting his or her farm. Since many weather events, such as drought or floods, which have an influence on the safety of fresh produce are relatively rare; maintaining historical records to inform the development of preventive controls specific to a given operation is invaluable. Similarly, proposed § 112.164(b) would establish that records that relate to the general adequacy of the equipment or processes being used by a farm, including the results of scientific studies and evaluations, must be retained at the farm for at least two years after the use of such equipment or processes is discontinued.

Certain growers and packers of covered produce currently retain records for at least two years. For example, produce operations certified by the National Organic Program must maintain their records relating to the production, harvesting, and handling of ''organic'' agricultural products for at least five years beyond the creation of the records (7 CFR 205.103). USDA's Agricultural Marketing Service requires that restricted use pesticide records be maintained for two years from the date of pesticide application (7 CFR 110.3). Under USDA's regulations implementing the Perishable Agricultural Commodities Act, 1930 (PACA), packers who pack and sell another firm's produce and growers and packers who voluntarily obtain a PACA license are required to preserve records for two years (7 CFR 46.14). Under the Florida Tomato Rule (''Tomato Good Agricultural Practices [T–GAP] & Tomato Best Management Practices'') (Ref. 262), firms must keep records documenting adherence to T–GAPs, ''including those addressing environmental review, water usage, record of completed education and training, pest control and crop production practices for the operation,'' for at least three calendar years (Ref. 44). Participants in the California Leafy Green Marketing Agreement (LGMA) must maintain their records kept under the LGMA agreement for two years (Ref. 45).

e. Acceptable Formats for Records

As proposed, § 112.165 would require that you keep records as either: (a) Original records; (b) true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or (c) electronic records in compliance

with part 11. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (*e.g.,* through the use of white-out). Proposed § 112.165 would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies is consistent with other regulations such as our Good Manufacturing Practices (GMPs) regulation for dietary supplements (§ 111.605(b)) and provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 112.165 also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by part 112 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under part 112. However, we request comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under part 112. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which we determined to be the case in the regulation Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (69 FR 71562; December 9, 2004 (the BT records regulation))? For the purposes of the records requirements in the BT records regulation, we concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, we exempted the records from the requirements of part 11 (21 CFR 1.329(b)). We also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR 189.5(c)(7) and 700.27(c)(7), respectively). We also seek comment on whether we should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

f. Making Records Available for Official Review

Proposed § 112.166(a) would require that you have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying. Our access to records required under this part would expedite efforts to document and ensure that covered produce is not adulterated, as well as to quickly and accurately identify any adulterated covered produce and prevent it from reaching consumers. For example, during a foodborne illness outbreak or contamination investigation, records access would help enable you and us to pinpoint the source and cause of contamination in a timely manner. This provision is consistent with our HACCP regulations for juice (§ 120.12(e)) and seafood (§ 123.9(c)), and dietary supplement GMPs (§ 111.610(b)), which require that all records required under those rulemakings be available for review and copying at reasonable times. This provision also is similar to requirements in the infant formula quality control procedures regulation (§ 106.100(l)) stating that manufacturers make readily available for authorized inspection all records required under those regulations. In addition, this proposed provision is similar to provisions in the juice HACCP regulation (§ 123.9(f)) and in the regulation on production, storage, and transportation of shell eggs (§ 118.10(d)) that require that firms be able to retrieve and provide any records stored offsite within 24 hours of request for official review.

Proposed § 112.166(b) would require that if you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, that you provide the records to us in a format in which they are accessible and legible. For example, you might provide us with an unencrypted copy of an electronic record or provide us with suitable equipment for viewing, printing, and copying a record. This provision would enable us to comprehend your records in a timely manner.

Consistent with proposed § 112.166(a), proposed § 112.166(c) would require that if your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods. Proposed § 112.166(c) is consistent with our HACCP regulations for seafood and juice, which provide for transfer of records for facilities closed for prolonged periods (between seasonal packs, in the case of juice) if the records could be immediately returned for official review upon request (§§ 123.9(b)(3) and 120.12(d)(3) for seafood and juice, respectively).

g. Disclosure Requirements

Proposed § 112.167 would specify that records required by this part are subject to the disclosure requirements under part 20 of this chapter. FDA's regulations in 21 CFR part 20, FOIA, the Trade Secrets Act [18 U.S.C. 1905], and the FD&C Act govern FDA's disclosures of information, including treatment of confidential commercial information and trade secret information. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule. Proposed § 112.167 is consistent with, but framed differently than, the disclosure provisions of the HACCP regulations for seafood and juice (§§ 123.9(d) and 120.12(f), respectively). Proposed § 112.167 is framed similarly to the disclosure provisions for records that must be kept under part 118 (Prevention of *Salmonella Enteritidis* in Shell Eggs During Production); under § 118.10(f), records required by part 118 are subject to the disclosure requirements under part 20.

P. Subpart P—Variances

1. Relevant Provisions of Section 419 of the FD&C Act

In section 419(c), the FD&C Act establishes criteria for the final regulation, including that the final regulation ''permit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to [section 419(c)(2) of the FD&C Act], where the State or foreign country determines that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed

under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 [of the FD&C Act] and to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(1)(F)). Section 419(c)(2) specifies the following:

''REQUESTS FOR VARIANCES.—A State or foreign country from which food is imported into the United States may in writing request a variance from the Secretary. Such request shall describe the variance requested and present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 402, and that the variance provides the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]. The Secretary shall review such requests in a reasonable timeframe'' (section 419(c)(2)(A)).

''APPROVAL OF VARIANCES.—The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons'' (section 419(c)(2)(B)).

''DENIAL OF VARIANCES.—The Secretary may deny a variance request if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulation adopted under [section 419(b) of the FD&C Act]. The Secretary shall notify the person requesting such variance of the reasons for the denial'' (section 419(c)(2)(C)).

''MODIFICATION OR REVOCATION OF A VARIANCE.—The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that such variance is not reasonably likely to ensure that the food is not adulterated under section 402 and is not reasonably likely to provide the same level of public health protection as the requirements of the regulations adopted under [section 419(b) of the FD&C Act]'' (section 419(c)(2)(D)).

2. Proposed Requirements

Consistent with the statutory provisions mentioned above, in this subpart, we propose a process by which variances from one or more requirements of part 112 may be requested by a State or foreign government, information that must accompany such requests, and the procedures and circumstances under which FDA may grant or deny such requests, and modify or revoke such variances. Variances approved by FDA would be limited to the requirements of part 112 specified by FDA, and have no effect on the application of other provisions of the FD&C Act.

Consistent with section 419(c)(2)(A) of the Act, proposed § 112.171 would establish that a State or foreign country from which food is imported into the U.S. may request a variance from one or more of the requirements proposed in part 112, where the State or foreign country determines that the variance is necessary in light of local growing conditions (proposed § 112.171(a)); and the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112 (proposed § 112.171(b)). Such a determination would likely be based on the particular crop, climate, soil, geographic, and environmental conditions of a particular region, as well as processes, procedures, or practices followed in that region. Given the diversity of covered produce commodities and covered activities subject to the requirements of part 112, we tentatively conclude that this provision provides sufficient flexibility while ensuring the same level of public health protection for covered produce. For example, a State or foreign country may consider that the historical performance of an industry within their jurisdiction (*e.g.,* as indicated by the epidemiological record) and the combination of measures taken by that industry merits requesting a variance from some or all provisions of this proposed rule. In requesting a variance, among other things, the State or foreign country would submit information that, while the procedures, processes and practices to be followed under the variance would be different from those prescribed in this proposed rule, the requested variance is reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and provide the same level of public health protection as the requirements of the final regulations (see proposed 112.173). FDA would encourage consideration of these kinds of submissions, and welcomes requests for pre-petition consultations, including meetings, with interested States or foreign governments to facilitate the development of variance petitions, including data and information that would be needed to demonstrate that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and provide the same level of public health protection as the requirements in this rule, when finalized. As discussed in section IV.K, FDA is proposing extended compliance dates for this proposed rule. We expect that these compliance periods would allow sufficient time for variance petitions to be developed, submitted, and reviewed by FDA. We request comment on the compliance periods.

In proposed § 112.172, we propose to establish that a request for a variance, as described in proposed § 112.171, must be submitted by the competent authority (*e.g.,* the regulatory authority for food safety) for the state or foreign government to FDA in the form of a citizen petition in accordance with 21 CFR 10.30.

In proposed § 112.173, we propose that, in addition to the requirements set forth in § 10.30, the Statement of Grounds (which is specified under § 10.30(b)) such petition requesting a variance must include a statement that the applicable State or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part (proposed § 112.173(a)). In addition, the Statement of Grounds would be required to describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of part 112 to which the variance would apply (proposed § 112.173(b)); and present information demonstrating that the procedures, processes, and practices to be followed under the variance requested are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112 (proposed § 112.173(c)). Under these provisions, a State or foreign country would be required to submit relevant and scientifically-valid information or materials specific to the covered produce or covered activity to support the petitioner's determination that the variance requested is reasonably likely

to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part. This would include information about the crop, climate, soil, and geographical or environmental conditions of a particular region, as well as the processes, procedures, or practices followed in that region.

Proposed § 112.174 establishes our presumption that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request. We do not believe that information exempt from disclosure under part 20 of this chapter is the type of information that FDA is requiring to be submitted in such a petition or that would be relevant in any comments submitted on such a petition. We also believe that providing full public access to this information is important to ensuring transparency and for the opportunity for states and foreign governments to request similar variances for similarly situated persons. Therefore, we expect to make these submissions publicly available.

Proposed § 112.175 would establish the Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director of the Office of Compliance, CFSAN as the responsible official for responding to a request for a variance from one or more requirements in proposed part 112.

Proposed § 112.176 would establish the general procedures applying to a petition requesting a variance from one or more requirements in proposed part 112. Proposed § 112.176(a) would provide that the procedures sets forth in § 10.30 govern the process by which FDA responds to a petition requesting a variance. Section 10.30 of this chapter specifies the requirements for any citizen petition submitted by a person (including a petitioner who is not a citizen of the United States) to FDA. Proposed § 112.176(b) would establish that, under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on the filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition). For example, similarly situated persons may include those whose farm operates under similar circumstances with similar procedures, processes, and practices as those covered by the petition. Proposed § 112.176(c) would establish that, under § 10.30(e)(3), FDA will respond to the petitioner in writing and will publish a notice on our Web site announcing our decision to either grant or deny the petition. Proposed § 112.176(c)(1) would establish that, if we grant the petition, either in whole or in part, we will specify the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply. Proposed § 112.176(c)(2) would establish that, if FDA denies the petition (including partial denials), FDA will explain the reason(s) for the denial in its written response to the petitioner and in the notice on our Web site announcing the decision to deny. Under proposed § 112.176(d), we propose to make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied). The provisions in proposed § 112.176 would ensure transparency in FDA's activities and decision-making, which allows the public to better understand the agency's decisions, increasing credibility and promoting accountability.

Proposed § 112.177 would establish circumstances under which an approved variance could apply to any person other than those identified in the petition requesting the variance. Under proposed § 112.177(a), a State or a foreign country that believes that a variance requested by a petition submitted by another State or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173. Moreover, under proposed § 112.177(b), we propose that if we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition. Consequently, under proposed § 112.177(c), if we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location. We tentatively conclude that the provisions in proposed § 112.177 ensure consideration of the application of variances to similarly situated persons to and provide for transparency and accountability in FDA's review of requests and decision-making.

Proposed § 112.178 would provide that we may deny a variance request if it does not provide the information required under proposed § 112.173 (including the requirements of § 10.30), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of this part. For example, we would expect to deny a petition if the State or foreign government failed to submit scientifically-valid data, information, or materials to demonstrate that the procedures, processes, or practices to be followed under the requested variance are reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112.

Proposed § 112.179 would specify that a variance approved by FDA becomes effective on the date of our written decision on the petition.

Under proposed § 112.180, we would be able to modify or revoke an approved variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of proposed part 112. For example, we may deem it necessary to modify terms and conditions of the variance based on a review of updated scientific data or factual information that is applicable to the covered produce and procedures, processes, or practices followed under the variance.

Proposed § 112.181 would establish the procedures that apply if FDA determines that an approved variance should be modified or revoked. Under § 112.181(a), we would provide notice of such a determination as follows: (1) We will notify a State or a foreign country directly, in writing at the

address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State or foreign country with an opportunity to request an informal hearing under part 16 of this chapter; (2) We will publish in the **Federal Register** a notice of our determination that a variance should be modified or revoked. This notice will establish a public docket so that interested parties may submit written submissions on our determination; and (3) When applicable, we will: (i) Notify in writing any States or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked; (ii) Provide those States or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and (iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States or foreign countries in which similarly situated persons are located.

Under § 112.181(b), we would consider submissions from affected States or foreign countries and from other interested parties as follows: (1) We will consider requests for hearings by affected States or foreign countries under part 16 of this chapter. If FDA grants a hearing, we will provide the State or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of hearing. If more than one State or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing); and (2) We will consider written submissions submitted to the public docket from interested parties.

Under § 112.181(c), we would provide notice of our final decision as follows: (1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter; and (2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

We tentatively conclude that these provisions are necessary not only to ensure transparency and accountability in FDA's activities and decision-making, but also to provide relevant parties with an opportunity for due process.

Finally, in proposed § 112.182, we would provide examples of permissible types of variances. These examples of variances from certain requirements in proposed part 112 are consistent with our proposed provisions in subpart B for alternatives from requirements in proposed part 112. A State or foreign government may request a variance from other requirements in proposed part 112, provided the conditions described in proposed § 112.171 are met.

3. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(1) to include Section 419(c)(2)(D) of the FD&C Act relating to the modification or revocation of a variance from the requirements of Section 419 of the FD&C Act, to the list of statutory and regulatory provisions under which regulatory hearings are available.

Q. Subpart Q—Compliance and Enforcement

1. Overall Strategy for Implementation and Compliance

FDA expects this proposed rule to improve produce safety to the extent the proposed requirements related to practices are actually implemented by farms. Many farms already follow some or all of the proposed practices, but we recognize that, when finalized, the proposed rule will be the first national standard for on-farm practices related to produce safety and that it will take time and a concerted, community-wide effort for the wide range of farms to come into full compliance. FDA is committed to working with the produce community and with partners in the U.S. Department of Agriculture, State agencies, and foreign governments to facilitate compliance through education, technical assistance and regulatory guidance.

We anticipate that compliance will be achieved primarily through the conscientious efforts of farmers, complemented by the efforts of State and local governments, extension services, private audits and certifications, and other private sector supply chain management efforts. We also recognize that the time needed to comply will vary, so we are proposing to phase in compliance dates based on farm size (see section IV.K of this document).

Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed to prevent significant hazards from entering the food supply or in response to produce safety problems, although FDA faces severe constraints in inspection and enforcement when it comes to foreign farms. FDA's inspection resources are very limited, however, in relation to the number of produce farms and the many other food production, processing and storage settings for which FDA has regulatory responsibility. Thus, as outlined below, FDA inspection will play an important but necessarily limited role in the overall compliance effort. FDA invites comment on all aspects of its compliance strategy.

2. Education, Technical Assistance and Regulatory Guidance

Education and technical assistance is the foundation of our intended compliance strategy. As discussed in section II.D. above, FDA has, together with USDA AMS, established a jointly-funded Produce Safety Alliance (PSA), a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce growers and packers with fundamental food safety knowledge. A first phase of PSA's work is intended to assist farms, especially small and very small farms, in establishing food safety programs consistent with the GAPs Guide and other existing guidances so that they will be better positioned to comply when we issue a final produce safety rule under section 419 of the FD&C Act. As this rulemaking progresses, FDA will work to ensure that the PSA materials are modified, as needed, to be consistent with the requirements of the produce safety rule. FDA intends to work with federal, State, and local officials, industry, and academia through the PSA to assist farmers to implement measures necessary to minimize the risk of serious adverse health consequences or death from consumption of covered produce.

We also will work to provide education and technical assistance through other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities, trade associations, and foreign partners and JIFSAN to reach farmers exporting covered produce into the U.S. in their local languages). We plan to work with these and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of the final rule.

FDA intends to further facilitate compliance with a final produce safety rule through the development and dissemination of guidance, in multiple

languages, on procedures, conditions, and practices that farms can implement to reduce the risk of known or reasonably foreseeable hazards. Section 419(e) of the FD&C Act requires FDA to develop guidance ''for the safe production and harvesting of specific types of fresh produce under [section 419]'' and to hold at least three public meetings in diverse geographical areas of the U.S. as part of an effort to conduct education and outreach regarding the guidance. Consistent with this statutory provision, FDA plans to develop guidance materials, including additional guidances specific to commodities, practices, and conditions, as needed and informed, in part, by stakeholder input, including that received during public meetings.

Section 419(a)(4) of FSMA states that ''the Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks which may include a history and severity of foodborne illness outbreaks.'' As discussed immediately above, we intend to fulfill this mandate by (1) conducting extensive outreach and educational efforts focused on the known risks of specific types of produce and specific types of agricultural practices applied to such produce; (2) focusing our inspection and enforcement efforts on farms that present the greatest risk based, in part, on past association with outbreaks, contamination, or the known risks of their agricultural practices and conditions and/or their specific types of produce; and (3) developing guidance materials related to the rule (including commodity-specific guidances) focused on known risks. We request comment on this approach and on specific strategies we should employ in order to best prioritize our implementation of the rule in this manner.

3. Supply Chain Management

FDA anticipates that significant incentives and accountability for compliance with a final produce safety rule will come through non-regulatory audits and supply chain management initiated by private entities.

As discussed in section II.F.2. of this document, a number of retail produce buyers currently require, as a condition of sale, that their produce suppliers comply with and be audited by third parties for conformance with the FDA GAPs guide. USDA AMS also offers a GAPs and Good Handling Practices (GAP&GHP) Audit Verification Program. USDA AMS and the California Department of Food and Agriculture (CDFA) have developed and are implementing the California Leafy Greens Marketing Agreement (CA LGMA) to protect public health via compliance with the food safety practices that are accepted by the LGMA board (Ref. 45). Compliance with such practices is further verified for members and signatories to the agreement through mandatory government audits by CDFA auditors who are trained and licensed by USDA AMS (Ref. 263). Leafy greens growers in Arizona have adopted a similar marketing agreement and audit structure for their growers (Ref. 32).

At the request of industry, the USDA AMS in 2009 held seven hearings throughout the United States to solicit input from the leafy greens industries across the U.S. regarding their desire to develop a proposed national marketing agreement for leafy greens. A decision regarding the proposed USDA AMS national marketing agreement for leafy greens is currently pending, but FDA and USDA are committed to working together to harmonize the provisions of any national or regional marketing agreements for produce with the provisions of any final rule FDA issues under section 419 of the FD&C Act. Rigorous audits conducted under national or regional marketing agreements can be an important tool for fostering compliance with the produce safety rule.

FDA also intends to issue notices of proposed rulemaking implementing sections 418 and 805 of the FD&C Act (sections 103 and 301 of FSMA). FDA is aware of the diversity in quality of audits and the need to strengthen that system, but we anticipate that audits will be an important source of accountability for compliance with a final produce safety rule.

4. Inspections

With a community as large and diverse as the produce farming industry, it is not reasonable to expect that industry-wide compliance can be gained primarily through inspection and enforcement, though, of course, inspection and enforcement must be a component of our efforts. Inspections will, of necessity, be targeted to those farms that present the greatest risk based, in part, on their association with past outbreaks or contamination events and the risk associated with the agricultural practices they apply in the growing, harvesting, packing, and holding of covered produce.

FDA intends to work collaboratively with our federal and State regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with a final produce safety regulation. Section 702(a)(1)(A) of the FD&C Act [21 U.S.C. 372(a)(1)(A)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. Qualified State, Territorial, or local regulatory officials may be commissioned or serve under contract with FDA to conduct examinations, inspections, and investigations for purposes of the FD&C Act. In addition, section 702(a)(2) [21 U.S.C. 372(a)(2)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through officers and employees of another Federal department or agency, subject to certain conditions set forth in that section. We expect to continue to cooperatively leverage the resources of federal, State, and local government agencies in this way as we strive to obtain industry-wide compliance with a final produce safety rule.

Section 419(b)(2)(A) of the FD&C Act specifically instructs FDA to ''provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States or the appropriate elected State official as recognized by State statute.'' Consistent with this provision and with the direction to improve the training of State, local, territorial, and tribal food safety officials under Section 1011 of the FD&C Act (21 U.S.C. 399c, added to the FD&C Act by section 209 of FSMA), FDA intends to work closely with extension and education organizations and State, local, territorial, and tribal partners to develop the tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements of a final produce safety rule. We expect to build on our collaboration with State, local, territorial, and tribal officials in the development of tools and training for use by inspectors in farm investigations on issues specific to food safety during growing, harvest, packing and holding produce.

FDA anticipates that some States may choose to adopt requirements modeled after the provisions of a final federal produce safety rule and may choose to perform inspections under their own authorities to enforce those provisions of their state laws. Such actions would further drive compliance with a final federal produce safety rule.

5. Comments Related to the Proposed Provisions

We received many comments on strategies for compliance, including comments from farmers, consumers, retail, State, federal and foreign governments, academia, trade associations and industry groups, and a non-profit research and advocacy organization. These comments broadly expressed strategies for compliance that included specific suggestions on how to ensure that all covered produce is in compliance with a final rule. Several comments recognized the importance of partnerships with respect to bringing about compliance with, and ultimately enforcing, a final rule. Comments urged the agency to work in cooperation with other federal, State, Territorial, tribal and local agencies with jurisdiction and expertise to ensure a coordinated and uniform approach to enforcement and compliance that will improve efficiency and effectiveness. Several comments noted that governmental testing laboratories should be recognized and funding should be provided to States to hire and train auditors.

We agree that partnerships will play a crucial role in bringing the produce industry into compliance with a final rule. As discussed in our overall strategy above and reflected in proposed 112.193, FDA intends to work with State, Territorial, tribal, and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements of a final produce safety rule. Education and outreach through mechanisms like PSA and other sources of information that are familiar to the produce farming community (such as Cooperative Extension, land grant universities, and trade associations) are the foundation of our intended compliance strategy. We also plan to work with these and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms, as they endeavor to comply with the provisions of a final rule. Of course, although much of our initial effort will be focused on education and outreach, we will also inspect farms on a targeted basis for compliance with a final produce safety rule. Partnerships will play an important role with regard to inspections as well. FDA intends to work collaboratively with our federal, State, Territorial, tribal, and local regulatory partners to use available inspection resources to conduct risk-based inspections of farms for compliance with the final regulation. FDA intends to further facilitate compliance with our final regulation through the development and dissemination of guidance on procedures, conditions, and practices that farms can implement to reduce the risk of known or reasonably foreseeable hazards.

Several comments noted that foreign governments could also play an important role in verifying compliance. Some noted that global recognition of food safety and food defense efforts should be developed. One country specifically requested that we recognize foreign fresh produce initiatives as equivalent oversight of the industry.

We agree that foreign governments will play an important part in bringing about compliance with a final produce rule with respect to foreign products. We have already begun to reach out to foreign governments regarding the requirements of FSMA and will continue to provide technical assistance as we move closer to finalizing rules issued under FSMA authorities. There are several provisions of FSMA that directly relate to these partnerships. Section 305 of FSMA specifically directs us to develop a plan to build the capacity of foreign governments with respect to food safety that will include, among other things, training of foreign governments on our requirements, provisions for mutual recognition of inspection reports, and provisions for multilateral acceptance of laboratory methods and testing and detection techniques. Under section 307 of FSMA, which added section 808 to the FD&C Act [21 U.S.C. 384d], we are directed to establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet certain requirements. Under that section, foreign governments or agencies of foreign governments, may be accredited as third party auditors who could help to ensure compliance with a final produce safety rule. Section 303 of FSMA amended section 801 of the FD&C Act to, among other things, allow us to designate an agency or representative of the foreign government of the country from which a food originated to provide certification or other assurances that certain foods are in compliance with the FD&C Act, if FDA chooses to require such certifications or assurances for certain foods. We are working to implement these provisions of FSMA. In addition, as set forth in subpart P of this proposed rule, foreign countries may request variances from requirements proposed in this rule, provided they meet certain conditions. See section V.P. of this document for further discussion of the process, conditions, and procedures related to a request for variance(s).

In addition to partnering with other U.S. agencies and foreign governments, several comments discussed the strength of industry programs imposed throughout the supply chain and urged us to leverage these private sector efforts. Some commented on the importance of verification of compliance by qualified and independent third parties and recognition of third party certification. These third parties could be those hired by industry, including retailers, to ensure the safety of produce from their suppliers. However, some comments identified duplicative audits and excessive documentation as problematic, particularly for small growers. Other comments recognized that importers can play an important role in verifying compliance with a final produce safety rule and safety of imported produce.

We agree that we should leverage the efforts of private supply chain management to further compliance with a final rule in this area. See discussion of our overall enforcement and compliance strategy immediately above. We also agree that importers will play an important role in ensuring the safety of produce grown in other countries and shipped to the United States. Under section 301 of FSMA, importers will have to verify that imported covered produce is produced in compliance with processes and procedures that provide the same level of public health protection as those required under section 419 of the FD&C Act.

Other comments noted that compliance with produce safety requirements should be tiered to reflect farm size, market requirements and risk. One comment noted that there should be dedicated inspectors for identified groups that may need additional assistance.

We agree that we should prioritize our compliance and enforcement efforts. As discussed above, we will be targeting our education efforts to the smaller businesses that may not be as familiar with our requirements as some of the larger farms. We also propose to give small and very small businesses extra time to comply with the final rule, as discussed in section IV.K of this document. With respect to inspections, they will, of necessity, be targeted to those farms that present the greatest risk based, in part, on their association with past outbreaks or contamination events and the risk associated with the agricultural practices they apply in the

growing, harvesting, packing, and holding of covered produce.

A few comments mentioned that research can play an important part in bringing about industry compliance. Some noted that foodborne illness outbreak investigations needed to be improved and used as educational opportunities to support food safety research. They noted that better investigative methods should be developed to help reveal possible sources of contamination. FDA agrees, as reflected in the recent establishment of the Coordinated Outbreak Response and Evaluation (CORE) Network, which is a permanent cadre of FDA experts whose full time responsibility is to enhance outbreak detection, response, and follow up investigations to inform future prevention efforts. CORE will work with CDC, state and local partners, and the food industry to investigate root causes of major outbreaks and share findings with the food safety community.

Comments also noted that a permanent institutional part of government should be developed to coordinate research, information, responses to, and control measures for, human pathogens and their evolution in the environment, including the farm environment, animal production, the industrial and commercial environment and the medical (healthcare) system. As discussed previously, we are pursuing regulatory science and research activities in collaboration with various partners. See section II.E. of this document for further information.

6. Proposed Requirements

Proposed § 112.191 states that the criteria and definitions in this part apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

As discussed in section III of this document, FDA proposes these regulations under the FD&C Act as amended by FSMA, and the Public Health Service Act (PHS Act). We note that section 419(c)(1)(A) of the FD&C Act provides that FDA shall establish in this rulemaking ''procedures, processes, and practices that the Secretary determines to be reasonably necessary * * * to provide reasonable assurances that the produce is not adulterated under section 402 [of the FD&C Act]'' and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 419(c)(1)(F), (c)(2)(A), (c)(2)(C), and (c)(2)(D). In sections V.A. through V.O. of this document, we explain how the proposed provisions are necessary to protect against contamination with hazards that may adulterate food. We tentatively conclude that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 112 in determining whether, under particular circumstances, a food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act. We also note 402(a)(4) of the FD&C Act provides that food is adulterated if it has been ''prepared, packed, or held under insanitary conditions'' whereby either of the proscribed results may occur. ''Prepared, packed, or held'' includes growing, harvesting, packing, and holding. The common meaning of ''prepare,'' as represented by the dictionary definition is, in relevant part, ''to make ready beforehand for some purpose, use, or activity * * * to put together'' (Ref. 264). Growing and harvesting are operations that make food ready for use as food. In addition, growing and harvesting at times involve holding of food.

Section 105(c) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding a new section—(vv)—to the list of acts and the causing thereof that are prohibited. Under section 301(vv), the following act, and the causing thereof, is prohibited: ''[t]he failure to comply with the requirements under section 419 [of the FD&C Act].'' To clearly communicate that failure to comply with regulations established under section 419 is a prohibited act, proposed § 112.192 would establish that the failure to comply with the requirements of part 112, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)).

Proposed § 112.193 provides that under Section 419(b)(2)(A) of the FD&C Act, FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials. As described above, we plan to work closely with State, Territorial, tribal, and local partners to develop the education and enforcement tools and training programs needed to facilitate consistent inspection and regulatory activities associated with the requirements proposed in subparts A through O.

R. Subpart R—Withdrawal of Qualified Exemption

As proposed, subpart R establishes the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of § 112.5. Specifically, proposed § 112.201 lists the circumstances under which FDA can withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specify the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provide for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211 provide a procedure for appeals, hearings, and decisions on appeals and hearings.

1. Requirements of Section 419 of the FD&C Act

Section 419(f)(3)(A) of the FD&C Act specifies that, ''[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm subject to an exemption under [section 419(f) of the FD&C Act], or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm, the Secretary may withdraw the exemption provided to such farm under [section 419(f) of the FD&C Act].'' Section 419 does not expressly prescribe the procedures for withdrawing a qualified exemption provided to a farm under section 419(f). We tentatively conclude that it is appropriate to be transparent about the process we would use to withdraw a qualified exemption and that we should include the process in the proposed rule.

2. Proposed Requirements

a. Circumstances for Withdrawal

Proposed § 112.201 would establish the circumstances under which FDA can withdraw an exemption applicable to a farm. Consistent with Section 419(f)(3)(A) of the FD&C Act, it states

that we may withdraw your qualified exemption under proposed § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm (proposed § 112.201(a)); or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (proposed § 112.201(b)).

Proposed § 112.201(a) would implement the statutory language of section 419(f)(3)(A) of the FD&C Act. An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. Food can become contaminated at many different steps in the farm-to-table continuum: On the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. When foodborne illness is associated with food, an investigation may enable us to directly link the illness to the farm that grew, harvested, packed, and/or held the food.

Proposed § 112.201(b) would also implement the statutory language of section 419(f)(3)(A) of the FD&C Act, which provides that FDA may withdraw a qualified exemption available to a farm under section 419(f) ''if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm.'' We tentatively conclude that the food to which this standard applies is food that would otherwise be covered produce, because that is the food that would be subject to this proposed rule if a qualified exemption is withdrawn. We also tentatively conclude that it is reasonable to interpret the word ''produced'' in this standard to refer to the activities within the farm definition other than harvesting, because this proposed rule would apply only to activities within the farm definition and the standard already uses the word ''harvested.'' Thus, proposed § 112.201(b) would provide that FDA may withdraw the qualified exemption applicable to a farm under proposed § 112.5 if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at such farm. As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a farm that grew, harvested, packed or held the food. If our investigation finds conduct or conditions associated with the farm that are material to the safety of the food that would otherwise be covered produce subject to proposed subparts B through O of this rule (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the qualified exemption applicable to the farm under proposed § 112.5 if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a farm to which the qualified exemption in proposed § 112.5 applies, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance, we would consider withdrawing the qualified exemption provided to the facility under proposed § 112.5 if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

b. Procedure for Issuance of Withdrawal Order

Proposed § 112.202(a) would provide that, if FDA determines that a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. We intend to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record. Proposed § 112.202(b) would require that an FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Directors and Director of the Center for Food Safety and Applied Nutrition are examples of an FDA official senior to the Director of the Office of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K (Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition is consistent with current FDA practices when dealing with foreign firms. Proposed § 112.202(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm. We tentatively conclude that it would be appropriate for FDA to issue an exemption withdrawal order to any of these persons. Proposed § 112.202(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

c. Information Included in FDA's Withdrawal Order

Proposed § 112.203(a) through (h) would require that an order to withdraw a qualified exemption applicable to a farm under § 112.5 include the following information:

(a) The date of the order (proposed § 112.203(a));

(b) The name, address and location of the covered farm (proposed § 112.203(b));

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm (proposed § 112.203(c));

(d) A statement that the farm must comply with subpart B through subpart O of this part on the date that is 60 calendar days after the date of the order (proposed § 112.203(d));

(e) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of subpart R of the rule (proposed § 112.203(e));

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 (21 CFR Part 16), with certain exceptions described in proposed § 112.208 (proposed § 112.203(f));

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and

the name of the FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); (proposed § 112.203(g)); and

(h) The name and the title of the FDA representative who approved the order (proposed § 112.203(h)).

FDA tentatively concludes that the requirements that we propose in § 112.203 would provide the owner, operator, or agent in charge of a farm subject to a withdrawal with adequate notice of the basis for our determination to withdraw the exemption and of their opportunity to appeal our determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393, orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16. We seek comments on the proposed process for withdrawal of a qualified exemption.

d. Requirements When a Withdrawal Order Is Issued

Proposed § 112.204 would require that the owner, operator, or agent in charge of a farm that receives an order to withdraw an exemption applicable to that farm under § 112.5 either (a) comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season; or (b) appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 112.206. We tentatively conclude that either of the two circumstances that could result in our determination that an exemption should be withdrawn (as described in proposed § 112.201) warrant prompt compliance with the rule in the interest of public health. We tentatively conclude that ten calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

e. Procedure for Appealing a Withdrawal Order (Including Requests for Informal Hearing)

Proposed § 112.205(a) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing would not prevent FDA from simultaneously detaining food from the farm under section 304(h) of the FD&C Act, seeking seizure of food from the farm under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act. Proposed § 112.205(b) would require that, if the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season. Proposed § 112.205(b) would make clear that the 60 calendar day time frame for compliance applies regardless of whether the owner, operator, or agent in charge of a farm requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of public health.

Proposed § 112.206(a) would require that, to appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must: (1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or, in the case of a foreign farm, to the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order; and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies. Allowing the owner, operator, or agent in charge of the farm to submit an appeal in person, by mail, email, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. Email and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the ten day time frame for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 112.206(a)(1) would repeat the 10 calendar day time frame that would be established in proposed § 112.204 and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. We are proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that we would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 112.206(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207. Requesting an informal hearing does not mean that a hearing will be held, because we may deny the request (see discussion of proposed § 112.207(b) below). However, if the owner, operator, or agent in charge of the farm does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the farm will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

Proposed § 112.207(a)(1) would provide that, if the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm may request an informal hearing. Proposed § 112.207(a)(1) would restate an option that would be included in proposed § 112.206(b) to highlight the opportunity to request an informal hearing. Proposed § 112.207(a)(2) would require that, if the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date of the order. We tentatively conclude that requiring submission of a request for an informal hearing in writing at the time

that the owner, operator, or agent in charge of the farm would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.207(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 112.207(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial. Under proposed § 112.206(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a genuine dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

f. Procedure for Appeals (Including Informal Hearings)

Proposed § 112.208(a) would establish that, if the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA. We tentatively conclude that, if we grant a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative time frame as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed 112.208(b) would establish that the presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate. We tentatively conclude that, if we grant a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.208(c)(1) through (7) would establish that, if the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 419 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that a qualified exemption provided to a farm under proposed § 112.5 should be withdrawn. However, we tentatively conclude as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a farm subject to withdrawal of the farm's qualified exemption. We also tentatively conclude that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a farm subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted. We seek comment on this proposed process.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 112.208(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing a qualified exemption provided under proposed § 112.5. The circumstances that may lead FDA to withdraw a qualified exemption include

an active investigation of a foodborne illness outbreak that is directly linked to a farm, or our determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at such farm. Such circumstances require prompt action. Under § 16.120, a farm that disagrees with FDA's decision to withdraw an exemption provided under § 112.5 has an opportunity for judicial review in accordance with § 10.45.

g. Presiding Officer

Proposed § 112.209 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of a qualified exemption applicable to a farm must be approved by a District Director or an official senior to a District Director. It is, therefore, necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the farm is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the farm is located, for example in the event the Regional Food and Drug Director for the region in which the farm is located is the FDA official who approved the withdrawal order. Any Office Director of FDA's Office of Regulatory Affairs could preside at a hearing, provided that the Office Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice.

h. Decisions on Appeals (Including Informal Hearings)

Proposed § 112.210(a) would require that, if the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 112.201, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm or if we determine that an exemption withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held by the farm. We tentatively conclude that we will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal.

Proposed § 112.210(b)(1) would require that, if the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within the 10-calendar day period after the hearing is held. We tentatively conclude that it is appropriate to grant the owner, operator, or agent in charge of a farm subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 112.211(d)) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 112.210(b)(2) would require that, if the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. We tentatively conclude that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the farm to come into compliance if we deny the appeal, and is in the interest of public health.

i. Revocation of Withdrawal Order

Proposed § 112.211(a) through (c) would establish that an order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time (proposed § 112.211(a)); or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time (proposed § 112.211(b)); or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time (proposed § 112.211(c)).

We tentatively conclude that an order to withdraw an exemption may be revoked in one of two manners. First, we are proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day time frame. Second, we are proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified time frames will also serve to revoke the order. We tentatively conclude that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

Proposed § 112.211(d) would establish that confirmation of a withdrawal order by the presiding

officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45 (21 CFR 10.45).

3. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(2) to include part 112, subpart R, relating to the withdrawal of a qualified exemption applicable to a farm, to the list of regulatory provisions under which regulatory hearings are available.

VI. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L.104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 265). FDA believes that the proposed rule will be an economically significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new provisions, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under Section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

F. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) are available to the public in the docket for this proposed rule (Ref. 265).

VII. Analysis of Environmental Impact

The agency has prepared a categorical exclusion determination relying upon the categorical exclusion at 21 CFR 25.30(j) and the determination that there are no extraordinary circumstances which raise the potential for this rule to individually or cumulatively have a significant effect on the human environment (Ref. 266). FDA requests comment on its analysis and determination. As set out in more detail in Section IX of this document, to the extent there are any environmental effects that FDA should take into consideration as it prepares a final rule, FDA requests public comment and supporting data or other information (*e.g.,* studies, data, reports). The agency will evaluate the information and input received in response to this proposed rule, including the specific questions listed in section IX of this document. Although FDA finds that no EIS is necessary for this proposed rule, if in response to comment received, FDA prepares an EA or EIS, it will provide notice and an opportunity for public review and comment on any such document.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Comments on proposed provisions and related issues—We seek comment on the need for, and appropriateness of, the various provisions proposed in this rule and our accompanying rationale. Specifically, we seek comment on the following issues:

- Proposed provisions in subpart A, including:
  - proposed §§ 112.1 and 112.2, including the produce that would be covered or not covered by the rule; the list of produce that would not be covered by the rule because it is rarely consumed raw (including asparagus, bok choy, and cranberries); and the proposed exemption for produce that receives commercial processing, including the types of processing that should qualify for this exemption;
  - proposed definitions in § 112.3(c), including those of agricultural water, hazard, reasonably foreseeable hazard, produce, humus, production batch of sprouts, and yard trimmings;
  - proposed definitions of small and very small businesses in § 112.3(b); as well as the proposed exclusion of certain farms from the scope of this rule based sales in § 112.4(a);
  - whether and how we should require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption;
  - the feasibility of the labeling provisions in proposed 112.6(b), particularly in the case of consolidating produce from several farm locations.
- Proposed general requirements in § 112.11, including on whether we should establish specific standards for any types of hazards that would be covered in proposed § 112.11 but for which we have not proposed specific standards in proposed subparts C through O; and the proposed allowance in § 112.12 for alternatives to certain specified requirements, including appropriateness of the list of permitted alternatives. Are there other proposed provisions for which we should permit alternatives and, if so, under what, if any, additional or different criteria than those proposed in § 112.12(b) and (c)?
- Proposed provisions in subparts C and D directed to personnel training, and health and hygiene, including the proposed requirements for training on principles of food hygiene and food safety, and for the maintenance of adequate personal cleanliness and hygienic practices when handling covered produce or food-contact surfaces during covered activities, including the provisions relevant to use of gloves and hand sanitizers;
- Proposed provisions directed to water, including those related to water quality, microbial indicators, and testing in §§ 112.41, 112.44, and 112.45; provision related to water sourced from public water systems in § 112.45(a); and recordkeeping in § 112.50; specifically:
  - Are the provisions in §§ 112.44–112.46 appropriately tailored to the risk posed by the manner in which the water is used?
  - Are the microbial standards specified in these provisions appropriate for the specified intended uses? For example, are the microbial standards appropriately tailored to uses such as direct application of irrigation water?
  - Are the provisions related to treatment of water sufficiently flexible to permit alternative safe uses of water that does not meet the specified microbial standard for its intended use?
  - Is there a need for a provision specifically related to disinfection treatment of re-circulated or single pass water used during and after harvest?
  - Are there any alternative options not considered in the proposed rule?
- Proposed provisions in subpart F directed to soil amendments, including those related to status, treatment, application restrictions, minimum application intervals, and recordkeeping (including the requirement related to documentation such as Certificates of Conformance); our focus on biological soil amendments of animal origin; any alternative options that we have not considered in this proposed rule; and the risk presented by the use of biological soil amendments in sprouting and whether that practice should be prohibited;
- Proposed provisions in subparts I, K, and L, including proposed § 112.81 related to the scope of applicability of subpart I, proposed § 112.114 related to dropped produce, and proposed § 112.115 related to measures to prevent formation of botulinum toxin; specifically:
  - Do you agree with our proposal to apply the proposed provisions in subpart I when covered activities take place in an outdoor area or a partially-enclosed building where there is a reasonable probability of contamination of covered produce, and our tentative conclusion that, accordingly, crops that grow completely underground would not be subject to the proposed provisions of subpart I?
  - With respect to dropped produce, should proposed § 112.114 apply to all commodities or should we provide for certain exceptions (and, if so, under what criteria)? Does proposed § 112.114 appropriately address produce (such as almonds) that is intentionally dropped to the ground during harvesting and where such harvesting does not cause bruising or damage to the produce? Should produce with peelable skin be excluded?
  - Is proposed § 112.115 a reasonably necessary measure to ensure the safety of packaged covered produce? Are there specific types or conditions of modified or reduced oxygen packaging methods that may or may not increase the risk of formation of botulinum toxin?
- Proposed provisions specific to sprouts in subpart M, including treatment of seeds and beans; microbial indicators and frequency of environmental monitoring; and requirement to establish and implement a written environmental monitoring plan (§ 112.144(a)) and sampling plan for each production batch of sprouts (§ 112.146(a)); as well as whether soil-grown sprouts should be subject to the proposed requirements, and whether and how to establish a supplier approval and verification program for seeds and beans used for sprouting;
- Proposed provisions in subpart N, including methods and allowance for alternative methods to be used provided they are at least equivalent to the proposed method in accuracy, precision, and sensitivity;
- Proposed requirements related to documentation and records in subpart O, including the requirement for a supervisor or responsible party to review certain records, and whether there are any circumstances that would warrant not applying part 11 to records that would be required to be kept under part 112;
- Proposed provisions in subpart P for variances, including related process and scientific data and information to

support a request for variance, and circumstances for approval or denial of a request for variance and for modification or revocation of an approved variance; Are there any specific concerns that we should consider in finalizing the procedures and processes for requests for variances, as applicable to foreign governments?

• Overall implementation and compliance strategy and proposed provisions in subpart Q, including specific strategies we should employ in order to best prioritize our implementation of the rule, and coordination of education and enforcement activities by relevant State, Territorial, tribal, and local authorities; and

• Proposed provisions in subpart R for withdrawal of a qualified exemption, including related process and timeframes for actions to be taken by FDA or farms.

• Regarding the scope of the recordkeeping requirements, are there alternative options that should be considered?

• Regarding the handwashing and toilet facility requirements, are our proposals reasonably consistent with current model practices or are there alternatives not considered in the proposed rule?

Regulatory approach—As discussed in section IV of this document, we have tentatively concluded that we should use a regulatory framework based on practices, procedures, and processes associated with growing, harvesting, packing, and holding of all covered produce. We considered and rejected the option to develop a framework that (based solely on a history of outbreaks or illnesses associated with the commodity) would be applicable to individual commodities or classes of commodities. Relevant references on the subject of produce safety, as well as the QAR, identify common on-farm routes of contamination, such as personnel training, health, and hygiene; domestic and wild animals; biological soil amendments of animal origin; agricultural water; and equipment and buildings. Procedures, processes and practices in each of these on-farm routes of contamination have the potential to introduce biological hazards into or onto any covered produce. Therefore, we are proposing an integrated approach to prescribe standards for each of these on-farm routes of contamination that we have tentatively determined are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act. We also recognize the need for additional standards specifically tailored to the growing, harvesting, packing and holding of sprouts, and have proposed minimum necessary standards for sprouts. We seek comment on our tentative conclusions related to this issue and the proposed regulatory approach described in section IV of the document. In addition, we seek comment on the following:

• Are there any alternative approaches that we should consider in establishing science-based minimum standards for the safe production and harvesting of produce and to minimize the risk of serious adverse health consequences or death?

• Are there specific commodities or categories of commodities that should be excluded from the scope of the rule, based on data related to their relative risk considerations? (Note that under our proposed integrated approach, we propose to exempt certain commodities, including a specified list of produce that is rarely consumed raw, and produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance; see section V.A.2.a. of this rule.)

• For example, the QAR ranked certain produce commodities, such as bananas and coconuts, as lower risk for illness, in part because such commodities are peeled or shelled before consumption in a manner that can be expected not to transfer contamination onto the interior, edible portion of the commodity. Should such commodities be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements?

• Certain commodities are ranked in the QAR as presenting a relatively lower likelihood of exposure, in part because such commodities have fewer potential routes of contamination and/or lower potential for contamination. In addition, some commodities are not known to have been associated with outbreaks. Some commodities (for example, pears, grapefruit, oranges, and lemons) meet both of these criteria, considering the rankings and outbreak data used in the QAR. Should commodities that meet both of these criteria be covered by the rule? Is coverage of these commodities unnecessary? Should they be covered but subject to a less stringent set of requirements? How should the rule address the changing nature of outbreak data over time?

• How should we account for uncovered commodities in considering a commodity-specific approach that relies on outbreak data?

• Are there pathogen surveillance data from sampling programs focusing on produce commodities that have no history of known outbreaks that would be useful in considering a commodity-specific approach?

• Can commodity characteristics be used as a basis to consider a commodity-specific approach? While the outbreak data show no consistent pattern that can be matched to commodity characteristics such as growth habit, our QAR shows that produce commodities that are ranked as higher risk of illness and those ranked as lower risk of illness do share some of the same characteristics. A further refinement of our assessment might be helpful in developing a commodity-specific approach based on commodity characteristics. Considering the qualitative nature of our assessment, are there quantitative data sets available that would enable a further refinement of our assessment?

• We seek comment on our tentative conclusion that produce in both direct market channels and other commercial channels are subject to the same routes of contamination, although the number of opportunities for contamination during packing and holding may be greater for produce in other commercial channels as compared to produce in direct market channels if there are greater numbers of touch points and handlers in these channels than there are in direct market channels.

• We seek comment on our tentative conclusion that because the statutory qualified exemption addresses market channels as a possible risk factor, and because we identified no data that would allow us to otherwise use market channels as a factor in covering and regulating produce under this proposed rule, we should not otherwise use market channels as a basis of risk categorization in this proposed rule.

• Are other data or information available that would be otherwise useful in considering a commodity-specific approach?

• We seek comment on the proposed effective and compliance dates.

• We seek comment on the appropriateness of the proposed exemptions and partial exemptions. Are there additional exemptions and relevant data to support such exemptions that we should consider?

Qualitative assessment of risk—We seek comment on the QAR, conclusions drawn from that assessment, and our consideration of those conclusions in developing the proposed requirements described in this rule. We also request

you to submit any data or factual information that may help the agency to conduct, as warranted, a thorough and robust quantitative assessment of risk associated with produce production and harvesting practices.

Chemical, physical or radiological hazards—We seek comment on our tentative conclusion that procedures, practices, and processes, which are proposed in this rule, are reasonably necessary to prevent the introduction of biological hazards only, and on whether, and to what extent, chemical, physical or radiological hazards should be covered within the scope of a final rule. Are there procedures, practices, or processes that minimize the risk of serious adverse health consequences or death and that are reasonably necessary to prevent the introduction of known or reasonably foreseeable chemical, physical or radiological hazards into produce or to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act?

Environmental testing for L. monocytogenes or Listeria spp for covered produce other than sprouts—Proposed § 112.143(a) would require testing the growing, harvesting, packing, and holding environment for sprouts for *Listeria* species or *L. monocytogenes;* however, we have not proposed to require environmental testing for other covered produce. A recent outbreak of listeriosis from cantaloupes attributed to insanitary conditions at a facility that washed, packed, cooled and held intact cantaloupes (Ref. 267) raises the question as to whether specific measures are necessary to minimize the risk posed by *L. monocytogenes* as an environmental pathogen. As discussed in section V.A. of this document, this proposed rule would not apply to off-farm facilities such as the facility associated with this cantaloupe outbreak— such facilities would instead be subject to part 110 and may be subject to section 418 of the FD&C Act. However, the same risk factors and potential measures for minimizing risk are relevant to both on-farm and off-farm produce washing, packing, cooling, and holding practices. Such measures could include environmental testing for *L. monocytogenes* or *Listeria* spp. to verify the adequacy of a covered farm's sanitation measures. Because *L. monocytogenes* is a ubiquitous microorganism, an intact fruit or vegetable could reasonably be expected to occasionally be positive for *L. monocytogenes.* Many studies have shown the presence of *L. monocytogenes* on fresh, intact produce, but there is limited epidemiological evidence associating listeriosis with produce, especially with intact fruits and vegetables (Ref. 268. Ref. 269. Ref. 270. Ref. 271. Ref. 272. Ref. 267). However, this recent outbreak indicates that intact produce can be a vehicle for listeriosis. What is not known is the extent to which, and under what circumstances, whole produce contaminated with *L. monocytogenes* presents a risk to consumers. The outbreak of listeriosis due to contamination of intact cantaloupes appears to have occurred due to a combination of factors, including pooled water on the floor of the facility, which was also difficult to clean, poorly designed equipment that was previously used for other commodities, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 273). The contribution of internalization of the organism and growth within the fruit is not known. Moreover, it is not known whether all of these circumstances are needed for *L. monocytogenes* to present a risk on produce or whether any one or more would have been sufficient. We also do not know the prevalence of *L. monocytogenes* environmental contamination of fruit and vegetable packing facilities (both on- and off-farm), nor do we know the prevalence of *L. monocytogenes* on produce washed, packed, cooled and stored in such facilities. We encourage research to answer these questions. We request comment on whether we should require, in a final rule, any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for *L. monocytogenes* or *Listeria* spp., and any criteria that should be employed to determine which farms should be subjected to such a requirement.

Operational assessment, food safety plans—As discussed in section IV of this document, while we recommend that farms conduct an operational assessment and develop a food safety plan, at this time, we are not proposing to require them to do so. We request comment on whether we should require, in a final rule, some or all covered farms to perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement.

Registration—We are also requesting comment about whether we should require, in a final rule, that covered farms, as described in proposed § 112.4(a), register with FDA. We are not aware of a nationwide database of farms, nor an accumulation of statewide databases, that would enable us to identify the names and locations of all entities subject to this proposed regulation. This would enable us to better provide outreach and technical assistance to covered entities. In addition, while inspection is intended to be only a relatively minor part of our overall compliance effort (see section V.Q. of the document for more information on our overall strategy), we anticipate performing inspections for enforcement purposes. We would use the covered farm registration information to create a database that we would use to allocate inspection resources. We are also interested in the existence of databases that could help us identify covered farms in the absence of a registration system, and in the appropriate data elements that should be collected in a registration system, should we decide to set up such a system.

Environmental issues—Consistent with § 25.50, FDA is involving the public in implementing its NEPA procedures applicable to this proposed rule. The agency will evaluate the information and input received in response to this proposed rule, including the specific questions below, to determine further actions, as appropriate.

Proposed subpart E would establish standards for an indicator organism in agricultural water applied to covered produce, and establish requirements for waters that do not meet those standards. We are soliciting comments on potential means or mechanisms for meeting the proposed standards. In your responses, please distinguish, to the extent appropriate, between sprouts and other covered produce.

1. Do farms that would be covered by the proposed rule, if finalized, currently treat water used for irrigation directly applied to covered produce other than sprouts, or water used to irrigate sprouts (whether or not it is directly applied)? We are seeking comments on pesticides used to reduce concentration of organisms of concern in water used for such irrigation and not pesticides used to prevent biofouling (chemigation).

2. What actions are currently being taken by farmers, either on their own or at the request of produce handlers or sellers to control the bacterial loads in water? Please provide data to support the information provided.

3. What water treatment methods do farmers use to clean their irrigation systems, how broadly are they used, and what are the effects on the environment? In what amounts or frequency are each of these methods applied? Please

provide data to support the information provided.

4. Do farms currently use municipal water sources to irrigate produce that would be covered by this proposed rule, if finalized? If so, please provide data on the use rate and prevalence of this practice, as well as data regarding effects on crop productivity of disinfection byproducts in municipal water used to irrigate produce that would be covered by the rule.

5. What sources of irrigation water (for example, municipal water, surface water and groundwater) are most frequently used? If more than one source is available, is there a preference for using one source over another? Please explain why.

In addition, we seek comment on potential effects of actions taken as a result of this rule on water rights/Tribal rights. Are water rights or Tribal rights likely to be affected by actions taken as a result of this rule? If so, how and to what extent?

Proposed subpart F would require the use of application method restrictions, application intervals, and/or treatment of biological soil amendments of animal origin to reduce exposure of covered produce to organisms of public health concern. We recognize that the requirements in this section may represent a departure from current practices.

1. How do farms that would be covered by the proposed rule, if finalized, currently manage solid animal waste? Manage liquid animal waste?

2. What is the prevalence of composting on farms using methods described in proposed subpart F? Please provide data or other available information on the frequency of such composting.

3. Are composting methods other than those described in proposed subpart F currently utilized on farms? To what extent? Please provide data or other available information on the frequency of such composting.

4. Are currently utilized methods of composting governed by state, county or local laws, ordinances or regulations? Please identify in your comments any relevant laws, ordinances, or regulations, and include copies if reasonably feasible.

5. What are the current laws, ordinances, or regulations in produce growing areas that govern manure handling and storage? How if at all do such laws, ordinances, or regulations address potential environmental effects from methane associated with manure? Ammonia? Nitrogen? Phosphorus?

Under proposed subpart F, manure may be chemically treated as an alternative to composting that would not require use of an application interval. We are also soliciting comments on available chemical treatment methods.

1. Do farms that would be covered by the proposed rule, if finalized, currently utilize chemical treatments to prevent or minimize pathogens in manure?

2. What types and quantities of chemicals are used for chemical treatment of manure? Please describe the treatment protocols, including application time, containment methods, and temperature requirements.

3. Please provide any data or other information relating to the effectiveness, and the relative effectiveness, of these chemical manure treatments, as well as any environmental effects of their use.

Proposed subpart I would apply when under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce. In such circumstances, proposed subpart I would require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and as needed during the growing season. If significant evidence of animal intrusion is found, these provisions would require farms to evaluate whether the covered produce can be harvested in accordance with proposed subpart K. Proposed subpart K would require taking reasonable measures to identify, and not harvest, covered produce that is reasonably likely to be contaminated, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. We are soliciting comments on current practices relevant to these provisions.

1. What measures, if any, are currently being implemented to prevent harvest of produce contaminated by excreta deposited by wild animals? If there are preferred measures, please explain the rationale for such preference. Please provide data to support the information provided.

2. Are farms removing vegetation bordering outdoor produce growing areas or drainages in an effort to deter wildlife from entering growing areas? If so, what is the current rate at which vegetation bordering outdoor produce growing areas or drainages is currently being removed? Are sediment basins or other conservation practices currently being removed and at what rate? Please provide data or other information to support the information provided.

3. To what extent have farmers taken action to exclude wildlife from outdoor produce growing areas? What measures are being used for these purposes, *e.g.* construction of fences or other physical barriers, chemical deterrents, or other mechanisms around growing areas to exclude wildlife? Please provide data or other information to support the information provided.

4. Has the implementation of measures to prevent animal intrusion negatively impacted habitat for rare or declining aquatic or terrestrial wildlife species or migratory birds? Please provide examples.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Chapter I be amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1:

■ a. In paragraph (b)(1), add an entry in numerical order.

■ b. In paragraph (b)(2), add an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 of the Federal Food, Drug, and Cosmetic Act (see part 112, subpart P of this chapter).

* * * * *

(2) * * *

§§ 112.201 through 112.211, (part 112, subpart R), relating to withdrawal of a qualified exemption.

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■ 3. Add part 112 to read as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Subpart A—General Provisions

Sec.

112.1 What food is covered by this part?
112.2 What produce is not covered by this part?
112.3 What definitions apply to this part?
112.4 Who is subject to the requirements of this part?
112.5 Who is eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?
112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?

Subpart B—General Requirements

112.11 What general requirements apply to persons who are subject to this part?
112.12 Are there any alternatives to the requirements established in this part?

Subpart C—Standards Directed to Personnel Qualifications and Training

112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces?
112.22 What minimum requirements apply for training personnel who conduct a covered activity?
112.23 What requirements apply regarding supervisors?
112.30 Under this subpart, what requirements apply regarding records?

Subpart D—Standards Directed to Health and Hygiene

112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?
112.32 What hygienic practices must personnel use?
112.33 What measures must I take to prevent visitors from contaminating covered produce and food-contact surfaces with microorganisms of public health significance?

Subpart E—Standards Directed to Agricultural Water

112.41 What requirements apply to the quality of agricultural water?
112.42 What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?
112.43 What treatment of agricultural water is required, and what requirements apply to treating agricultural water?
112.44 What testing is required for agricultural water, and what must I do based on the test results?
112.45 How often must I test agricultural water that is subject to requirements of § 112.44?
112.46 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?
112.50 Under this subpart, what requirements apply regarding records?

Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?
112.52 How must I handle, convey, and store biological soil amendments of animal origin?
112.53 What prohibitions apply regarding use of human waste?
112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?
112.55 What microbial standards apply to the treatment processes in § 112.54?
112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?
112.60 Under this subpart, what requirements apply regarding records?

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—Standards Directed to Domesticated and Wild Animals

112.81 How do the requirements of this subpart apply to areas where covered activities take place?
112.82 What requirements apply regarding domesticated animals that I allow to graze in fields or use as working animals where I grow covered produce?
112.83 What requirements apply regarding animal intrusion?

Subpart J—[Reserved]

Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding Activities

112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?
112.112 What measures must I take during harvest activities?
112.113 How must I handle harvested covered produce during covered activities?

112.114 What requirements apply to dropped covered produce?
112.115 What measures must I take when packaging covered produce?
112.116 What measures must I take when using food-packing (including food packaging) material?

Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation

112.121 What equipment and tools are subject to the requirements of this subpart?
112.122 What buildings are subject to the requirements of this subpart?
112.123 What requirements apply regarding equipment and tools subject to this subpart?
112.124 What requirements apply to instruments and controls used to measure, regulate, or record?
112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?
112.126 What requirements apply to my buildings?
112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?
112.128 What requirements apply regarding pest control in buildings?
112.129 What requirements apply to toilet facilities?
112.130 What requirements apply for hand-washing facilities?
112.131 What must I do to control and dispose of sewage?
112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?
112.133 What requirements apply to plumbing?
112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?
112.140 Under this subpart, what requirements apply regarding records?

Subpart M—Standards Directed to Sprouts

112.141 What requirements apply to seeds or beans used to grow sprouts?
112.142 What measures must I take for growing, harvesting, packing, and holding sprouts?
112.143 What testing must I do during growing, harvesting, packing, and holding sprouts?
112.144 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?
112.145 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?
112.146 What must I do to collect and test samples of spent sprout irrigation water or sprouts?
112.150 Under this subpart, what requirements apply regarding records?

Subpart N—Analytical Methods

112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.45?
112.152 What methods must I use to test the growing environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.143(a) and § 112.144?

Subpart O—Requirements Applying to Records That You Must Establish and Keep

112.161 What general requirements apply to records required under this part?
112.162 Where must I store records?
112.163 May I use existing records to satisfy the requirements of this part?
112.164 How long must I keep records?
112.165 What formats are acceptable for the records I keep?
112.166 What requirements apply for making records available and accessible to FDA?
112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Subpart P—Variances

112.171 Who may request a variance from the requirements of this part?
112.172 How may a State or foreign country request a variance from one or more requirements of this part?
112.173 What must be included in the Statement of Grounds in a petition requesting a variance?
112.174 What data and information submitted in a petition requesting a variance are publicly available?
112.175 Who responds to a petition requesting a variance?
112.176 What process applies to a petition requesting a variance?
112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?
112.178 Under what circumstances may FDA deny a petition requesting a variance?
112.179 When does a variance approved by FDA become effective?
112.180 Under what circumstances may FDA modify or revoke an approved variance?
112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?
112.182 What are the permissible types of variances that may be granted?

Subpart Q—Compliance and Enforcement

112.191 How do the criteria and definitions in this part apply to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act?
112.192 What is the result of a failure to comply with this part?
112.193 What are the provisions for coordination of education and enforcement?

Subpart R—Withdrawal of Qualified Exemption

112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?
112.202 What procedure will FDA use to withdraw an exemption?
112.203 What information must FDA include in an order to withdraw a qualified exemption?
112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?
112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?
112.206 What is the procedure for submitting an appeal?
112.207 What is the procedure for requesting an informal hearing?
112.208 What requirements are applicable to an informal hearing?
112.209 Who is the presiding officer for an appeal and for an informal hearing?
112.210 What is the timeframe for issuing a decision on an appeal?
112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 112.1 What food is covered by this part?

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list—arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams;

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership; and

(3) Produce that is not a raw agricultural commodity.

(b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:

(1) The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;

(2) You must establish and keep documentation in accordance with the requirements of subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and

(3) The requirements of this subpart and subpart Q of this part apply to such produce.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of food (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of food (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination. The term ''biological soil amendment of animal origin'' does not include any form of human waste.

Composting means a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131°F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership. Covered activity does not include manufacturing/processing within the meaning defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term ''covered produce'' refers to the harvestable or harvested part of the crop.

Curing means the maturation stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.

Farm means a facility (as defined in § 1.227 of this chapter) in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. Farm includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed

on that farm or another farm under the same ownership; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food-contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes food-contact surfaces of equipment and tools used during harvest, packing and holding.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as humus, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological agent that is reasonably likely to cause illness or injury in the absence of its control.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Humus means a stabilized (*i.e.,* finished) biological soil amendment produced through a controlled composting process.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when applicable, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than excreta) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any

plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (*e.g.,* a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user with respect to a food means the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State as the farm that produced the food; or

(ii) Not more than 275 miles from such farm. The term ''consumer'' does not include a business.

Raw agricultural commodity (RAC) means ''raw agricultural commodity'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Reasonably foreseeable hazard means a potential hazard that may be associated with the farm or the food.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of ''sewage sludge'' in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Static composting means a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Surface water means all water which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You means a person who is subject to some or all of the requirements in this part.

§ 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as ''food'' defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.

(b) You are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Who is eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) You are eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) you sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?

(a) If you are eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

(1) This subpart A; and

(2) Subparts Q and R of this part.

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise

be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (b)(2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

Subpart B—General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to the following specific requirements of this part, provided that you satisfy the requirements of paragraphs (b) and (c) of this section:

(1) The requirements in § 112.44(c) for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method;

(2) Composting treatment processes established in § 112.54(c)(1) and (c)(2);

(3) The minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives; and

(4) The minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application.

(b) You may establish and use an alternative to any of the requirements listed in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part (including meeting the same microbiological standards, where applicable), and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval.

(c) Scientific data and information used to support an alternative to a requirement listed in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part.

Subpart C—Standards Directed to Personnel Qualifications and Training

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must have the training, in combination with education or experience to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that should not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be

responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart C in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D—Standards Directed to Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

(a) You must take measures to prevent contamination of covered produce and food-contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as a communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

(1) Excluding any person from working in any operations that may result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and

(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food-contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food-contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, clean cloth towels, sanitary towel service or other adequate hand drying devices:

(i) Before starting work;

(ii) Before putting on gloves;

(iii) After using the toilet;

(iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards; and

(4) If you choose to use gloves in handling covered produce or food-contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so.

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food-contact surfaces with microorganisms of public health significance?

(a) A visitor is any person (other than personnel) who enters your covered farm with your permission.

(b) You must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(c) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Standards Directed to Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, you must inspect the entire agricultural water system under your control (including water source, water distribution system, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

(1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent or nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(c) You must adequately maintain all agricultural water distribution systems as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(d) You must immediately discontinue use of a source of agricultural water and/or its distribution system, and not use the water source and/or its distribution system when you have determined or have reason to believe that your agricultural water is not safe and of adequate sanitary quality for its intended use, until you either:

(1) Re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and test the water to determine if your changes were effective and to ensure that your agricultural water is safe and of adequate sanitary quality for its intended use; or

(2) Treat the water in accordance with the requirements of § 112.43.

(e) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of pooling of water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What treatment of agricultural water is required, and what requirements apply to treating agricultural water?

(a) You must treat any agricultural water that you use (such as with an EPA-registered antimicrobial pesticide product) if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use.

(b) Any method you use to treat agricultural water to satisfy the requirement in paragraph (a) of this section must be effective to make the water safe and of adequate sanitary quality for its intended use.

(c)(1) You must deliver any treatment of agricultural water required by paragraph (a) of this section in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

(2) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?

(a) You must test the quality of agricultural water according to the requirements in § 112.45 using a quantitative, or presence-absence method of analysis provided in subpart N of this part to ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water when it is:

(1) Used as sprout irrigation water;

(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;

(3) Used to make a treated agricultural tea;

(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or

(5) Used for washing hands during and after harvest activities.

(b) If you find that there is any detectable generic *E. coli* in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in accordance with the requirements of § 112.43.

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic *E. coli* per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the requirements established in paragraph (c) of this section, provided you satisfy the requirements of § 112.12.

§ 112.45 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every three months thereafter during the growing season, except that there is no requirement to test water when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44, you must test the water as specified in the table in this paragraph.

If the untreated surface water is—	Then you must test the untreated surface water—
(1) From any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake).	At least every 7 days during the growing season.

If the untreated surface water is—	Then you must test the untreated surface water—
(2) From any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm man-made water reservoir).	At least once each month during the growing season.

§ 112.46 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce);

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for build-up of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart E in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of any analytical tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1);

(4) Documentation of the results of water treatment monitoring under § 112.43(c)(2);

(5) Documentation of the results of water testing you perform to satisfy the requirements of § 112.44; and

(6) Scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d).

(7) Annual documentation of the results or certificates of compliance from a public water system under 112.45(a)(1) or (a)(2), if applicable.

Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials used to make the tea have been so processed and the water used to make the tea satisfies the requirements of 112.44(a).

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of 112.44(a);

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that has become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (for example, thermal), chemical process (for example, high alkaline pH), or combination of scientifically valid controlled physical and chemical processes that has been demonstrated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7;

(b) A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms; or

(c) A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms. Scientifically valid controlled composting processes include:

(1) Static composting that maintains aerobic (*i.e.,* oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 days

and is followed by adequate curing, which includes proper insulation;

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or

(3) Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative process has been demonstrated to satisfy the microbial standard in § 112.55(b).

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For *L. monocytogenes, Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph or;

For the microorganism—	The microbial standard is—
(1) *L. monocytogenes*	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion.
(2) *Salmonella* species	Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis).
(3) *E. coli* O157:H7	Less than 0.3 MPN per 1 gram analytical portion.

(b) Less than three MPN *Salmonella* species per four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application	9 months.
(ii) Untreated	In a manner that does not contact covered produce during or after application	0 days.
(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (*i.e.,* no restrictions)	0 days.
(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application	0 days.
(4)(i) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application	45 days.
(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b).	In a manner that does not contact covered produce during or after application	0 days.

(b) You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of § 112.12.

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart F in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) Documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment;

(2) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring;

(ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and

(iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and

location to minimize the risk of contamination by an untreated or in-process biological soil amendment of animal origin;

(3) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved;

(4) Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3); and

(5) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—Standards Directed to Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply when a covered activity takes place in a fully-enclosed building.

§ 112.82 What requirements apply regarding domesticated animals that I allow to graze in fields or use as working animals where I grow covered produce?

At a minimum, if you allow animals to graze or use them as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must take the following measures:

(a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and

(b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

§ 112.83 What requirements apply regarding animal intrusion?

(a) If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:

(i) Your covered produce; and

(ii) Your observations and experience; and

(2) Immediately prior to harvest.

(b) If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112.

Subpart J—[Reserved]

Subpart K—Standards Directed to Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (*i.e.,* excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce; and

(b) Adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b). Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground.

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use.

(b) If you reuse food-packing material, you must take steps to ensure that food-contact surfaces are clean, such as by cleaning and sanitizing, when necessary, food-packing containers or using a clean liner.

Subpart L—Standards Directed to Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of undesirable microorganisms or other contamination. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and

(b) Storage sheds, buildings, or other structures used to store food-contact

surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and

(b) Equipment and tools must be:

(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces, and

(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food-contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(d)(1) You must inspect, maintain, and clean and sanitize, when necessary and appropriate, all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination, must be:

(a) Accurate and precise as necessary and appropriate in keeping with their purpose;

(b) Adequately maintained; and

(c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

(a) Adequately clean before use in transporting covered produce; and

(b) Adequate for use in transporting covered produce.

§ 112.126 What design and construction requirements apply to my buildings?

All of the following design and construction requirements apply regarding buildings.

(a) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards. Buildings must:

(1) Provide sufficient space for placement of equipment and storage of materials;

(2) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food-contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and

(3) Be constructed in such a manner that floors, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.

(b) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food-contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food-contact surfaces, or food-packing material is exposed; or

(2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food-contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food-contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

(1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;

(2) Be directly accessible for servicing, be serviced and cleaned on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

(1) Soap (or other effective surfactant);

(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and

(3) Adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use hand antiseptic/sanitizer or wipes as a substitute for soap and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities.

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

(1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart L, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart L in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

(1) Growing operations for sprouts; and

(2) Covered harvesting, packing, or holding activities.

Subpart M—Standards Directed to Sprouts

§ 112.141 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) If your farm grows seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) If you know or have reason to believe that a lot of seeds or beans have been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts.

(c) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

§ 112.142 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food-contact surfaces you use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.

(c) You must treat seeds or beans that will be used to grow sprouts using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm.

§ 112.143 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.144.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* species in accordance with the requirements of § 112.146; or

(2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts), test each production batch of sprouts at the in-process stage (*i.e.,* while sprouts are still growing) for *E. coli* O157:H7 and *Salmonella* species in accordance with the requirements of § 112.146.

§ 112.144 What requirements apply to testing the environment for Listeria species or L. monocytogenes?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes.*

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes.*

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (*i.e., Listeria* species or *L. monocytogenes);*

(2) How often you will collect environmental samples, which must be no less than monthly; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must collect environmental samples and test them for *Listeria* species or *L. monocytogenes* according to the method in § 112.152.

§ 112.145 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes?

You must take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional microbial sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;

(d) Conduct finished product testing when appropriate; and

(e) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.146 What must I do to collect and test samples of spent sprout irrigation water or sprouts?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts:

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for *E. coli* O157:H7 and *Salmonella* species using a method that has been validated for its intended use (testing spent sprout irrigation water or sprouts) to ensure that the testing is accurate, precise, and sensitive in detecting these pathogens.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart M in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm;

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.144;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.146(a);

(4) The results of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152; and

(6) The testing method you use in accordance with the requirements of § 112.146(b).

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.45

(a) You must test the quality of water using a method of analysis:

(1) As published in the ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) International'' (18th ed., revision 4, 2011) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*; or

(2) As published in the Standards Methods for the Examination of Water and Wastewater (21st ed., 2005), American Public Health Association (APHA), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the APHA, 800 I St. NW., Washington, DC 20001, 202–777–2742. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*; or

(3) As prescribed in Chapter 4 of the FDA Bacteriological Analytical Manual (BAM) (Edition 8, Revision A, 1998), as updated in June 2011. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 4 (Edition 8, Revision A, 1998), as updated in June 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and

Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*; or

(4) That is at least equivalent to the appropriate method of analysis in §§ 112.151(a)(1), (a)(2) or (a)(3) in accuracy, precision, and sensitivity.

§ 112.152 What methods must I use to test the growing environment for Listeria species or L. monocytogenes to satisfy the requirements of § 112.143(a) and § 112.144?

You must test the growing environment by testing for the presence of *Listeria* species or *L. monocytogenes* in environmental samples using the methods and procedures described in Chapter 10 of FDA's Bacteriological Analytical Manual (BAM) April 2011, Edition (Edition 8, Revision A, 1998), or a method that is at least equivalent in accuracy, precision, and sensitivity. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 10—''*Listeria monocytogenes,* Detection and Enumeration of *Listeria monocytogenes* in Foods,'' April 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240–402–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html*.

Subpart O—Requirements Applying to Records That You Must Establish and Keep

§ 112.161 What general requirements apply to records required under this part?

(a) All records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) When records are required to be established and kept in subparts C, E, F, L, and M of this part (§§ 112.30, 112.50, 112.60, 112.140, and 112.150), you must establish and keep documentation of actions you take when a standard in those subparts is not met.

(c) Records required under §§ 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted after 6 months following the date the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

Yes. The regulations in this part do not require duplication of existing records if those records contain all of the information required by this part.

§ 112.164 How long must I keep records?

(a) You must keep records required by this part for 2 years past the date the record was created.

(b) Records that relate to the general adequacy of the equipment or processes being used by a farm, including the results of scientific studies and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records, in compliance with part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.

(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside FDA?

Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P—Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the

competent authority (*e.g.,* the regulatory authority for food safety) for a State or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State or a foreign country that believes that a variance requested by a petition submitted by another State or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and § 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the **Federal Register**. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(3) When applicable, we will:

(i) Notify in writing any States or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States or foreign countries with an opportunity to request

an informal hearing under part 16 of this chapter; and

(iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of hearing.

(ii) If more than one State or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

Examples of permissible types of variances include:

(a) Variance from the requirements, established in § 112.44(c), when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method.

(b) Variance from the process conditions, established in § 112.54(c)(1), for static composting;

(c) Variance from the process conditions, established in § 112.54(c)(2), for turned composting;

(d) Variance from the minimum application interval, established in § 112.56(a)(1), for an untreated biological soil amendment of animal origin; and

(e) Variance from the minimum application interval, established in § 112.56(a)(4), for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(c).

Subpart Q—Compliance and Enforcement

§ 112.191 How do the criteria and definitions in this part apply?

The criteria and definitions in this part apply in determining whether a food is adulterated:

(a) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(b) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.192 What is the result of a failure to comply with this part?

The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under Section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

We may withdraw your qualified exemption under § 112.5:

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(b) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) If FDA determines that a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of this subpart;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(h) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season; or

(b) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 60 calendar days of the date of the order, or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00123 Filed 1–4–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. FDA also is proposing to revise certain definitions in FDA's current regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for ''farms.'' FDA is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in the FD&C Act. The proposed rule is intended to build a food safety system for the future that makes modern, science-, and risk-based preventive controls the norm across all sectors of the food system.

DATES: Submit either electronic or written comments on the proposed rule by May 16, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 15, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0920 and/or RIN 0910–AG36, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
- Purpose and Coverage of the Proposed Rule
- Summary of the Major Provisions of the Proposed Rule
- Costs and Benefits

I. Introduction
II. Background
- A. Regulatory Framework for Human Food
- B. FDA Food Safety Modernization Act
- C. Preventive Controls and Hazard Analysis and Critical Control Points (HACCP) Systems
- D. Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding Food for Human Consumption

E. The Role of Testing as a Verification Measure in a Food Safety System
F. The Role of Supplier Approval and Verification Programs in a Food Safety System
III. Legal Authority
A. Changes to Current 21 CFR Part 1, Subparts H, I, and J
B. Changes to Current 21 CFR Part 110
C. Hazard Analysis and Risk-Based Preventive Controls
IV. Public Meeting and Preliminary Stakeholder Comments
A. Introduction
B. Comments on Allergen Control
C. Comments on Accredited Laboratories
D. Comments on Environmental Monitoring and Product Testing
E. Comments on Flexibility of Regulations and Guidance
F. Comments on Food Defense
G. Comments on Guidance and Outreach
H. Comments on Preventive Controls
I. Comments on Small and Very Small Business
J. Comments on Submission of Food Safety Plan to FDA
K. Comments on Modified Requirements for Warehouses
V. Placement of Regulatory Requirements
VI. Highlights of the Proposed Rule
A. Overview
B. Proposed Revisions to 21 CFR Part 1, Subparts H, I, and J
C. Proposed Revisions to General Provisions of 21 CFR Part 110 (Part 110) (Proposed Part 117, Subpart A)
D. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)
E. Proposed New Requirements for Hazard Analysis and Risk-Based Preventive Controls (Proposed Part 117, Subpart C)
F. Proposed New Provisions for Modified Requirements (Proposed Part 117, Subpart D)
G. Proposed New Provisions for Withdrawal of an Exemption Applicable to a Qualified Facility (Proposed Part 117, Subpart E)
H. Proposed New Recordkeeping Requirements (Proposed Part 117, Subpart F)
VII. Compliance Dates
VIII. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities
A. Section 103(c) of FSMA
B. The Current Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act
C. Why This Rulemaking Is Needed
D. Organizing Principles for How the Status of a Food As a Raw Agricultural Commodity or As a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act
E. Proposed Revisions to 21 CFR Part 1
F. Impact of Proposed Revisions to the Definitions in 21 CFR Part 1
G. Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition
H. Results of the Qualitative Risk Assessment
I. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 418 of the FD&C Act
J. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 421 of the FD&C Act
IX. Proposed General Revisions to Current Part 110
A. Title
B. Proposed Redesignations
C. Proposed Revisions for Consistency of Terms
D. Proposed Additions Regarding Cross-Contact
E. Proposed Revisions for Consistency With the Definition of ''Food''
F. Proposed Revisions To Address Guidance in Current Part 110
G. Proposed Editorial Changes
X. Proposed Revisions to General Provisions of Part 110 (Proposed Part 117, Subpart A)
A. Proposed § 117.1—Applicability and Status
B. Proposed § 117.3—Definitions
C. Proposed § 117.5—Exemptions
D. Proposed § 117.7—Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That is Not Exposed to the Environment
XI. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)
A. Proposed Deletion of Guidance From Current Part 110
B. Other Potential Revisions to Current Guidance
C. Proposed Revisions for Consistency of Terms
D. Proposed Revisions To Address Cross-Contact
E. Proposed and Potential Revisions to Current § 110.10—Personnel (Proposed § 117.10)
F. Proposed Revisions to Current § 110.20—Plant and Grounds (Proposed § 117.20)
G. Proposed Revisions to Current § 110.35—Sanitary Operations (Proposed § 117.35)
H. Proposed Revisions to Current § 110.37—Sanitary Facilities and Controls (Proposed § 117.37)
I. Proposed Revisions to Current § 110.40—Equipment and Utensils (Proposed § 117.40)
J. Proposed Revisions to Current § 110.80—Processes and Controls (Proposed § 117.80)
K. Proposed Revisions to Current § 110.93—Warehousing and Distribution (Proposed § 117.93)
L. Proposed Revisions to Current § 110.110—Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard (Proposed § 117.110)
M. Potential Revisions to Establish Requirements in Place of Current Guidance
N. Request for Comment on Additional CGMP Requirements
XII. Proposed New Requirements for Hazard Analysis and Risk-Based Preventive Controls (Proposed Part 117, Subpart C)
A. Proposed § 117.126—Requirement for a Food Safety Plan
B. Proposed § 117.130—Hazard Analysis
C. Proposed § 117.135—Preventive Controls for Hazards That Are Reasonably Likely To Occur
D. Proposed § 117.137—Recall Plan for Food With a Hazard That Is Reasonably Likely To Occur
E. Proposed § 117.140—Monitoring
F. Proposed § 117.145—Corrective Actions
G. Proposed § 117.150—Verification
H. Proposed § 117.155—Requirements Applicable to a Qualified Individual
I. Proposed § 117.175—Records Required for Subpart C
J. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed
K. Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act
XIII. Proposed New Provisions for Modified Requirements (Proposed Part 117, Subpart D)
A. Proposed § 117.201—Modified Requirements That Apply to a Qualified Facility
B. Proposed § 117.206—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment
XIV. Proposed New Provisions for Withdrawal of an Exemption Applicable to a Qualified Facility (Proposed Part 117, Subpart E)
A. Requirements of Section 418 of the FD&C Act
B. Proposed § 117.251—Circumstances That May Lead FDA To Withdraw an Exemption Applicable to a Qualified Facility
C. Proposed § 117.254—Issuance of an Order To Withdraw an Exemption Applicable to a Qualified Facility
D. Proposed § 117.257—Contents of an Order To Withdraw an Exemption Applicable to a Qualified Facility
E. Proposed § 117.260—Compliance With, or Appeal of, an Order To Withdraw an Exemption Applicable to a Qualified Facility
F. Proposed § 117.264—Procedure for Submitting an Appeal
G. Proposed § 117.267—Procedure for Requesting an Informal Hearing
H. Proposed § 117.270—Requirements Applicable to an Informal Hearing
I. Proposed § 117.274—Presiding Officer for an Appeal and for an Informal Hearing
J. Proposed § 117.277—Time Frame for Issuing a Decision on an Appeal
K. Proposed § 117.280—Revocation of an Order To Withdraw an Exemption Applicable to a Qualified Facility
L. Proposed § 117.284—Final Agency Action
M. Conforming Amendments to 21 CFR Part 16
XV. Proposed New Recordkeeping Requirements (Proposed Part 117, Subpart F)
A. Relevant Statutory Provisions
B. Proposed § 117.301—Records Subject to the Requirements of this Subpart F

C. Proposed § 117.305—General Requirements Applying to Records
D. Proposed § 117.310—Additional Requirements Applying to the Food Safety Plan
E. Proposed § 117.315—Requirements for Record Retention
F. Proposed § 117.320—Requirements for Official Review
G. Proposed § 117.325—Public Disclosure
XVI. FSMA's Rulemaking Provisions
A. Requirements in Section 418(n)(3) of the FD&C Act Regarding Content
B. Requirements in Section 418(n)(5) of the FD&C Act Regarding Review of Hazard Analysis and Preventive Controls Programs in Existence on the Date of Enactment of FSMA
XVII. Proposed Removal of 21 CFR Part 110—Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food
XVIII. Proposed Conforming Amendments
XIX. Preliminary Regulatory Impact Analysis
A. Overview
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement Fairness Act of 1996
D. Unfunded Mandates Reform Act of 1995
E. Paperwork Reduction Act of 1995
F. Public Access to the Analyses
XX. Analysis of Environmental Impact
XXI. Federalism
XXII. Comments
XXIII. References
Appendix
I. The Role of Testing as a Verification Measure in a Modern Food Safety System
A. Verification of Preventive Controls
B. Scientifically Valid Sampling and Testing
C. Verification Testing of Raw Materials and Ingredients
D. Verification of Sanitation Controls to Significantly Minimize or Prevent the Potential for an Environmental Pathogen to Contaminate Food
E. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen to Contaminate Food
F. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls
G. Metrics for Microbiological Risk Management
II. The Role of Supplier Approval and Verification Programs in a Food Safety System
III. References

Executive Summary

Purpose and Coverage of the Proposed Rule

The proposed rule would revise FDA's current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it would add new preventive controls provisions as required by the FDA Food Safety Modernization Act (FSMA). In general, with some exceptions the new preventive controls provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions. Second, the proposed rule would update, revise, or otherwise clarify certain requirements of our CGMP regulations, which were last updated in 1986.

In addition, this proposed rule would clarify the scope of the exemption for ''farms'' in FDA's current food facility registration regulations and make corresponding clarifications to FDA's current regulations for the establishment, maintenance, and availability of records. These clarifications would affect who would be subject to the current regulations for registration and recordkeeping as well as the new preventive controls requirements that would be established by this proposed rule.

To put these changes in context, and to provide legal, regulatory, scientific, and technical information relevant to the new provisions, we provide several sections of background. This background discusses the history of food regulation and current regulatory framework, provides an overview of the provisions of FSMA applicable to this proposed rule, explains the principles and history of the use of Hazard Analysis and Critical Control Point (HACCP) systems, and describes a variety of hazards that have been associated with foods and food safety problems (including outbreaks of foodborne illness) that have resulted from these hazards. An Appendix also describes the role of testing as a verification measure in a food safety system, and the role of supplier approval and verification programs in a food safety system.

Summary of the Major Provisions of the Proposed Rule

The proposed rule would implement the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the proposed rule would establish requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls for hazards that are reasonably likely to occur;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

The application of the preventive controls would be required only in cases where facilities determine that hazards are reasonably likely to occur. We do not expect that all possible preventive measures and verification procedures would be applied to all foods at all facilities.

The proposed rule would also establish a series of exemptions (including modified requirements in some cases) from the requirements for hazard analysis and preventive controls. Facilities that manufacture, process, pack or hold food and that are required to register with FDA under section 415 of the FD&C Act would be required to comply with the proposed regulation unless they are covered by an exemption. The table immediately below summarizes these proposed exemptions in general terms. Importantly, the table in this Executive Summary does not include all the details that you must consider to determine whether an exemption applies to you. We provide those details in the proposed regulation (proposed § 117.5) and explain them in section X.C of this document.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what would be exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
"Qualified Facility" as defined by FSMA:	FDA is proposing three options for defining "very small business" and requests comment on which to adopt in a final rule.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS—Continued

Who or what would be exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
• Business with average annual sales of < $500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or.	Modified requirements would apply—i.e., a qualified facility would be required to: • Notify FDA about its status; and • Either: ○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or ○ Notify FDA that it complies with applicable local regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.
• Very small business. • Option 1: Average annual sales of < $250,000. • Option 2: Average annual sales of < $500,000. • Option 3: Average annual sales of <$1,000,000.	
• Low risk, on farm activities performed by small business (< 500 employees).	Small and very small on-farm businesses conducting these low risk activities would be exempt from most of the rule's requirements.
-or-	
• Low-risk, on-farm activities performed by a very small business ○ Option 1: very small = <$250,000. ○ Option 2: very small = <$500,000. ○ Option 3: very small = <$1,000,000.	We would define the low-risk activities that qualify for the exemption, including the specific foods to which they relate (such as re-packing intact fruits and vegetables, or grinding/milling/cracking/crushing grains)
Activities that are subject to the seafood HACCP requirements of part 123 (21 CFR part 123).	The facility must be in compliance with part 123.
Activities that are subject to the juice HACCP requirements of part 120 (21 CFR part 120).	The facility must be in compliance with part 120.
Activities that are subject to the "low-acid canned food" requirements of part 113 (21 CFR part 113).	• The exemption applies only with respect to microbiological hazards. • The facility must be in compliance with part 113.
The manufacturing, processing, packing, or holding of a dietary supplement that is subject to the CGMP requirements of part 111 (21 CFR part 111).	• The facility must be in compliance with part 111. • The facility must be in compliance with requirements for serious adverse event reporting for dietary supplements
Activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).	Elsewhere in this issue of the Federal Register, FDA is proposing standards for produce safety.
Alcoholic beverages at a facility that is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States.	The exemption also would apply to food other than alcoholic beverages at such a facility, provided that the food is in prepackaged form and constitutes not more than 5 percent of the overall sales of the facility.
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.	A facility that stores raw agricultural commodities that are fruits and vegetables would not be exempt.
A facility solely engaged in the storage of packaged food that is not exposed to the environment.	Modified requirements would apply for the storage of refrigerated packaged food.

The proposed rule also would establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption. The proposed rule would establish requirements that would apply to all records that would be required by the various proposed provisions. The proposed recordkeeping provisions would implement specific requirements of FSMA regarding records associated with the new provisions for hazard analysis and risk-based preventive controls and would allow facilities to show, and FDA to determine, compliance with the regulatory requirements.

The proposed rule would require that a qualified individual prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of a food safety plan. The proposed rule also would establish minimum requirements for the "qualified individual," who would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Only a trained individual or individual qualified by job experience is capable of effectively executing these activities.

FDA is requesting comment on when and how other elements of a preventive controls system are an appropriate means of implementing the statutory directives, including: a product testing program, an environmental monitoring program, and a supplier approval and verification program, as appropriate.

Costs and Benefits

We summarize the domestic annualized costs of the three options for the proposed rule in the table immediately below. We are unable to estimate the benefits of the proposed rule. Instead we show the Breakeven Illness Percentage for each of the three options for the proposed rule. This is calculated by dividing the number of illnesses that would have to be prevented annually under each option by the total estimated number of illnesses attributable to FDA-regulated food products under the scope of each option of the proposed rule. This

ignores the costs to foreign firms and benefits to foreign consumers.

	Total domestic costs annualized at 7 per cent over 7 years	Annual breakeven illness percentage
Proposed Rule with Very Small Business Defined as Less Than or Equal to $250,000 in Annual Revenue.	$475 million	24
Proposed Rule with Very Small Business Defined as Less Than or Equal to $500,000 in Annual Revenue.	$395 million	20
Proposed Rule with Very Small Business Defined as Less Than or Equal to $1,000,000 in Annual Revenue.	$319 million	16

I. Introduction

Each year, about 48 million Americans (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to recent estimates from the Centers for Disease Control and Prevention (CDC). This is a significant public health burden that is largely preventable. While many illnesses are the result of improper food handling practices in the home and food service settings, which would not be addressed by this proposed rule, FDA believes that improvements to its current good manufacturing practice (CGMP) regulations in part 110 (21 CFR part 110), including those prescribed by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–533), can play an important role in reducing foodborne illness.

FSMA, signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides us with new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and directs us to build an integrated national food safety system in partnership with State, local, tribal, and territorial authorities.

This new law continues efforts by the food industry and government to protect and improve the safety of the nation's food supply. At the Federal level, these efforts go back to the Pure Food and Drug Act of 1906, the United States' first national food safety law. FSMA carries forward the basic principle embodied in the 1906 law that food establishments have the primary responsibility and capacity to make food safe and that government's role is to set standards for food safety and provide oversight to help ensure standards are met.

Since passage of the 1906 Act, and the most recent revision of its basic food safety provisions in the Federal Food, Drug, and Cosmetic Act of 1938, the combined efforts of the food industry and government have produced a set of standards and practices that make the U.S. food supply among the safest in the world. These efforts include the development and adoption by FDA of CGMP standards that have long provided the regulatory foundation for food safety. They also include, in more recent years, the adoption for some elements of the food supply of more targeted, risk-based approaches, such as the Hazard Analysis and Critical Control Points (HACCP) approach to food safety.

HACCP was pioneered by the food industry and reflects the understanding that food safety is best assured if each producer and processor understands the hazards that are reasonably likely to occur in their particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate the hazard. FDA has by regulation required seafood and juice processors to implement the HACCP approach to preventive controls. The U.S. Department of Agriculture (USDA) has also mandated HACCP for meat and poultry processors, and many food companies have implemented such modern preventive control systems for other commodities.

While these efforts have contributed to progress on food safety, and the United States has one of the safest food supplies in the world, significant food safety challenges persist in today's complex, dynamic, and global food system. Today's food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. New pathogens are emerging, and we are seeing commonly known pathogens appear in foods where they have not been traditionally seen. The population of individuals at greater risk for foodborne illness, such as those who are immune-compromised, is increasing. When illness outbreaks occur, they can have devastating impacts on public health and impose substantial economic disruption and cost on the food industry. The food safety challenge is only compounded by globalization, which has resulted in approximately 15 percent of the U.S. food supply being imported, including 80 percent of our seafood, 50 percent of our fresh fruit, and 20 percent of our vegetables.

Congress responded to today's food safety challenges by enacting FSMA. FSMA builds on past experience and the strong foundation provided by the current food safety system, but it also marks an historic turning point for food safety. FSMA directs FDA to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system; meets the food safety challenges of the global food system; and establishes stronger partnerships for food safety across all levels of government and with the private sector to ensure optimal use of public and private resources. FDA has embarked on a comprehensive effort to build the food safety system mandated by Congress, as described on its FSMA implementation web page at *http://www.fda.gov/fsma*.

A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and FDA's ability to oversee their implementation for both domestic and imported food. These include, among others, regulations establishing preventive control standards for human food and animal food facilities, produce safety standards, standards that define the accountability of importers to verify the safety of food produced overseas, and a new program for accrediting public and private bodies to provide credible certifications that regulated entities are meeting U.S. safety standards. A proposed rule on foreign supplier verification is closely interconnected to this rule on preventive controls for human food, and is expected to publish soon.

In this document, we propose standards to implement the requirement in section 103 of FSMA for the adoption of preventive controls in human food facilities. The preamble that follows provides critical background on FDA's previous efforts in establishing and implementing CGMPs and preventive controls, because these past efforts are the critical starting point and foundation for FSMA implementation. The preamble then explains and provides background on the rationale for our proposed updating of current CGMP requirements and for the new rules implementing FSMA's preventive controls requirement. We are seeking comments on all aspects of this proposal.

II. Background

A. Regulatory Framework for Human Food

1. Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

In the **Federal Register** of April 26, 1969, FDA issued a final rule to establish in 21 CFR part 128 CGMP requirements for the manufacturing, processing, packing, or holding of human food (34 FR 6977). The CGMP regulation established criteria for effective sanitation control in the manufacture, processing, packing, or holding of human foods to effect compliance with section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), under which food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (33 FR 19023, December 20, 1968). In 1973, we amended the CGMP regulation by adding a new section regarding natural or unavoidable defect levels in foods. (38 FR 854, January 5, 1973). In 1977, we redesignated the CGMP regulation as part 110 (21 CFR part 110) (42 FR 14301 at 14338, March 5, 1977).

In the **Federal Register** of June 19, 1986, FDA issued a final rule to revise the CGMP regulation in part 110 (hereinafter current part 110) (51 FR 22458). That final rule established new, updated, and more detailed CGMP requirements for food industry personnel; plants and grounds; sanitary facilities, controls, and operations; equipment and utensils; processes and controls; warehousing and distribution; and natural or avoidable defect levels (51 FR 22458). During the rulemaking to establish current part 110, we clarified that the CGMP regulations also identify the applicable criteria for implementing the requirements of section 402(a)(3) of the FD&C Act (21 U.S.C. 342(a)(3)), such that compliance with the CGMP requirements is also required to ensure that food does not consist in whole or in part of any filthy, putrid, or decomposed substance, or are otherwise unfit for food (51 FR 22458 at 22462). In addition, we noted that the CGMP requirements in part 110 serve two purposes: (1) To provide guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated; and (2) to state explicit, objective requirements that enable industry to know what FDA expects when an investigator visits one of its plants (51 FR 22458 at 22459).

In the rulemaking to establish current part 110, we also invoked section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which authorizes FDA to issue regulations for any requirements that, in the Commissioner's judgment, are necessary to prevent the introduction, transmission, or spread of food-borne communicable diseases from one State to another (44 FR 33238 at 33239, June 8, 1979). As we noted in that rulemaking, ''[b]ecause this authority is designed to eliminate the introduction of diseases * * * from one State to another, this authority must of necessity be exercised upon the disease-causing substance within the State where the food is manufactured, processed, or held,'' and that ''[d]ue to the nationwide, interrelated structure of the food industry, communicable diseases may, without proper intrastate food controls, easily spread interstate'' (44 FR 33238 at 33239).

Current part 110 serves as an ''umbrella'' regulation applicable to the manufacturing, processing, packing, or holding of all human food, with the exception that it does not apply to establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities (RACs) which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to consumers (§ 110.19(a)).

In 2002, FDA convened a CGMP Modernization Working Group (the CGMP Working Group) to determine whether part 110 is in need of further revision. The CGMP Working Group initiated research programs, presented preliminary findings, and solicited public comments, data, and scientific information through three public meetings (69 FR 40312, July 2, 2004). In 2005, the CGMP Working Group issued a report (hereinafter the CGMP Working Group Report) summarizing the oral and written comments we received in response to the **Federal Register** notice announcing the public meetings, as well as our key findings (Ref. 1).

The CGMP Working Group Report presented seven ''opportunities'' for CGMP modernization. The report called for:

- Requiring appropriate training for food production supervisors and workers, including the maintenance of personnel training records;
- Requiring the creation and implementation of a written food allergen control plan for food processing establishments that handle major food allergens;
- Requiring a written environmental pathogen control program, including the maintenance of appropriate implementation records, for food processors that produce ready-to-eat foods that support the growth of the pathogenic microorganism *Listeria monocytogenes;*
- Requiring food processors to develop and maintain written cleaning and sanitation procedures, at a minimum for all food-contact equipment and food-contact surfaces, that define the scope, cleaning or sanitation objective, management responsibility, monitoring, corrective action, and recordkeeping associated with the cleaning or sanitation procedure;
- Considering whether to remove the current exemption for facilities solely engaged in the harvesting, packing, storage, and distribution of RACs by requesting further public comment on this issue;
- Requiring food processors to maintain certain critical records that document that controls and systems that ensure food safety are being properly implemented and requiring that FDA be given access to such documents to verify compliance with the CGMP requirements; and
- Requesting further public comments and suggestions regarding how the use of time-temperature relationships can be incorporated into CGMP regulations or guidances for proper refrigerated storage or hot holding (Ref. 1).

2. Other Food Safety Regulations Established by FDA

Although the umbrella CGMP requirements of current part 110 apply to the full range of human food, FDA concluded over time that they do not directly address unique safety issues associated with the manufacturing, processing, packing, or holding of certain specific types of food products. We therefore promulgated additional food safety regulations to provide for

specific process controls for the manufacturing, processing, packing, or holding of certain specific foods that are not captured by the more general part 110 CGMP requirements. Currently, such specific food safety regulations include those for:

- Thermally processed low-acid foods packaged in hermetically sealed containers (i.e., ''low-acid canned foods,'' hereinafter referred to as LACF) (part 113 (21 CFR part 113)) (Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as ''cans,'' the term ''low-acid canned foods'' has been used for decades as a shorthand description for ''thermally processed low-acid foods packaged in hermetically sealed containers,'' and we continue to use that term and its abbreviation, LACF, for the purposes of this document);
- Acidified food (part 114 (21 CFR part 114));
- Bottled drinking water (part 129 (21 CFR part 129));
- Infant formula (parts 106 and 107 (21 CFR parts 106 and 107));
- Fish and fishery products (part 123 (21 CFR part 123));
- Juice (part 120 (21 CFR part 120));
- Dietary supplements (part 111 (21 CFR part 111));
- Refrigeration of shell eggs held for retail distribution (§ 115.50 (21 CFR 115.50); and
- Production, storage, and transportation of shell eggs (part 118) (21 CFR part 118)).

We discuss these food safety regulations immediately below.

a. Acidified food and LACF. In the **Federal Register** of January 24, 1973, FDA issued a final rule (the canned food CGMP regulation) to establish specific CGMP requirements to address safety issues unique to the manufacturing, processing, packing, and holding of thermally processed foods packaged in hermetically sealed containers (38 FR 2398). In the **Federal Register** of May 14, 1973, we issued a final rule to establish an emergency permit control regulation, in accordance with section 404 of the FD&C Act (21 U.S.C. 344), to serve as an enforcement mechanism for the canned food regulation (38 FR 12716). In the **Federal Register** of January 29, 1974, we issued a final rule to establish procedures to implement the emergency permit control enforcement mechanism (39 FR 3748). The emergency permit control regulation is currently codified in 21 CFR part 108.

In 1979, we issued a final rule to revise the canned food CGMP regulation and separate it into two distinct regulations. One of these regulations, established in part 113, is directed to the safe manufacturing, processing, packing, and holding of LACF (44 FR 16209, March 16, 1979). The second regulation, established in part 114, is directed to the safe manufacturing, processing, packing, and holding of acidified foods (44 FR 16230, March 16, 1979). Acidified foods are low-acid foods to which acid(s) or acid food(s) are added; they have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below; and certain foods are excluded from the coverage of part 114 (21 CFR 114.3(b)). In the **Federal Register** of March 16, 1979, we also issued an emergency permit control regulation to serve as an enforcement mechanism for the new acidified foods regulation (44 FR 16204).

In establishing the regulations for LACF and acidified foods, FDA determined that CGMP regulations specific to LACFs and acidified foods are necessary to control the presence of *Clostridium botulinum* (*C. botulinum*), a bacterium commonly found in soil that can form spores that are capable of prolonged survival under adverse conditions and produce a botulinum toxin under anaerobic conditions, such as those in canned foods (41 FR 30442, July 23, 1976). Botulinum toxin can cause botulism, a rare but serious paralytic illness that can be fatal and is considered a medical emergency (Ref. 2). The primary factors that determine the formation and growth of *C. botulinum* in food are pH, water activity, and storage conditions, and LACFs and acidified foods can pose a risk of botulism if these critical factors are not carefully controlled (44 FR 16209).

Part 113 establishes requirements for equipment; control of components, food product containers, closures, and in-process material; production and process controls; and records and reports for LACF. Part 114 establishes requirements for production and process controls and records and reports for acidified foods. In light of the severity of the hazard presented by botulinum toxin, parts 113 and 114 require that supervisory personnel be trained at schools approved by FDA (§§ 113.10 and 114.10, respectively).

The enforcement regulations in §§ 108.25 and 108.35 require manufacturers, processors, and packers of acidified foods and LACF, respectively, to file food canning establishment registration information with FDA. The registration information must include, among other things: the name, principal place of business, and the location of the establishment engaged in the manufacturing, processing, or packing of acidified foods or LACF; processing methods; and a list of the foods prepared at the establishment (§§ 108.25(c) and 108.35(c), respectively). Under the procedural enforcement regulations of subpart A of part 108, if after an investigation we determine that a manufacturer, processor, or packer of acidified foods or LACF is not in compliance with the requirements of §§ 108.25 or 108.35, respectively, we may issue an order requiring that the entity apply for and obtain a temporary emergency permit from us, which we might or might not issue, before introducing any acidified food or LACF into interstate commerce. Subpart A of part 108 also establishes the criteria and procedures related to a determination of the need for an emergency permit, revocation of the determination of need for an emergency permit, issuance or denial of an emergency permit, and suspension and reinstatement of an emergency permit.

b. Bottled drinking water. In the **Federal Register** of November 26, 1973, FDA issued a final rule to establish quality standard regulations establishing allowable levels for microbiological, physical, chemical, and radiological contaminants in bottled drinking water (38 FR 32558). The quality standard regulation is codified at 21 CFR § 165.110(b). In the **Federal Register** of March 12, 1975, we issued a final rule to establish CGMP requirements for the processing and bottling of bottled drinking water (40 FR 11566). The bottled water CGMP regulation is codified in part 129 (21 CFR part 129).

FDA promulgated part 129 in light of surveys and analyses of field investigations that we and the U.S. Environmental Protection Agency (EPA) conducted in 1971 and 1972. The surveys and analyses revealed, among other things, that some bottled water failed to meet some of the prevailing regulatory criteria for non-bottled, public drinking water (38 FR 1019 at 1019, January 8, 1973), some of the bottling plants surveyed did not conduct adequate bacteriological and chemical analyses of their products, and in other cases, bottling was not performed under sanitary conditions (38 FR 32563).

Part 129 requires that bottled water be safe and that it be processed, bottled, held, and transported under sanitary conditions. Processing practices addressed in part 129 include the protection of the water source from contamination, sanitation at the bottling

facility, and quality control to ensure the safety of the water. Part 129 also establishes certain analytical testing requirements for chemical, physical, radiological, and microbiological contaminants.

c. Infant formula. The Infant Formula Act of 1980 (the 1980 infant formula act) (Pub. L. 96–359) amended the FD&C Act to include section 412 (21 U.S.C. 350a) and was intended to improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. Enactment of the law resulted largely from the emergence of a substantial number of cases involving a serious medical disorder known as hypochloremic metabolic alkalosis, which is most frequently characterized by an infant's inability to thrive. The illnesses were found to be associated with prolonged exclusive use of soy protein-based infant formulas that lacked adequate amounts of the essential nutrient, chloride (45 FR 86362 at 86362, December 30, 1980).

In response to the 1980 act, FDA issued final rules to establish the following regulations regarding infant formula:

- Subpart B of part 106 (21 CFR part 106, subpart B) regarding infant formula quality control procedures (47 FR 17016, April 20, 1982);
- Subpart D of part 107 (21 CFR part 107, subpart D) regarding infant formula recalls (47 FR 18832, April 30, 1982);
- Subpart B of part 107 (21 CFR part 107, subpart B) regarding the labeling of infant formula (50 FR 1833, January 4, 1985);
- Subpart C of part 107 (21 CFR part 107, subpart C) regarding exempt infant formula (50 FR 48183, November 22, 1985);
- Subpart D of part 107 (21 CFR part 107, subpart D) regarding nutrient requirements for infant formulas (50 FR 45106, October 30, 1985).

In 1986, Congress amended section 412 of the FD&C Act as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99–570) (the 1986 infant formula amendments) to address concerns regarding the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. In 1989, FDA issued revised recall regulations in subpart E of part 107 (54 FR 4006, January 27, 1989), and in 1991, FDA issued regulations in § 106.100 to implement the provisions of the 1986 infant formula amendments for records and record retention (56 FR 66566, December 24, 1991).

In the **Federal Register** of July 9, 1996, FDA issued a proposed rule to implement the remaining provisions of the 1986 infant formula amendments (61 FR 36154). Specifically, we proposed to amend the existing infant formula regulations in parts 106 and 107 to: (1) Establish CGMPs, including microbiological testing; (2) revise the quality control procedures in part 106 to ensure that an infant formula contains the level of nutrients necessary to support infant growth and development; (3) specify audit procedures to ensure compliance with CGMP and quality control procedure regulations; (4) establish requirements for quality factors to ensure that required nutrients will be in a bioavailable form; (5) establish batch and CGMP recordkeeping requirements; (6) specify submission requirements for registration and notification to FDA before the introduction of an infant formula into interstate commerce; and (7) update 21 CFR part 107 to reflect the 1986 amendments. In 2002 and 2003, FDA held three Food Advisory Committee meetings (67 FR 12571, March 19, 2002; 67 FR 63933; October 16, 2002; 68 FR 8299; February 20, 2003). FDA reopened the comment period for the proposed rule twice (68 FR 22341, April 28, 2003; and 71 FR 43393, August 1, 2006). FDA is developing a final rule.

d. Fish and fishery products. In the **Federal Register** of December 18, 1995, FDA issued a final rule to establish in part 123 procedures for the safe and sanitary processing and importing of fish and fishery products (60 FR 65096). Part 123 requires seafood processors to develop, implement, and document sanitation control procedures and mandates the application of HACCP procedures. In the remainder of this document, the phrases ''seafood HACCP regulation'' and ''HACCP regulation for seafood'' refer to part 123. We discuss the HACCP concept in more detail in section II.C of this document. We describe the seafood HACCP regulation in more detail in section II.C.5.a of this document.

e. Juice. In the **Federal Register** of January 19, 2001, FDA issued a final rule to establish in part 120 (21 CFR part 120) requirements to ensure the safe and sanitary processing and importation of fruit and vegetable juices and juice products by mandating the application of HACCP principles to the processing of these foods (66 FR 6138). In the remainder of this document, the phrases ''juice HACCP regulation'' and ''HACCP regulation for juice'' refer to part 120. We describe the juice HACCP regulation in more detail in section II.C.5.c of this document.

f. Dietary supplements. The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103–417) among other things added section 402(g) to the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) in part authorizes the Secretary of HHS to promulgate regulations to prescribe CGMPs for dietary supplements. Section 402(g)(2) also stipulates that such regulations must be modeled after existing CGMP regulations for food.

In the **Federal Register** of June 25, 2007, FDA issued a final rule to establish in part 111 (21 CFR part 111) CGMP requirements for the manufacturing, packaging, labeling, and holding of dietary supplements to ensure their quality (72 FR 34752). FDA established part 111 because the umbrella food CGMP provisions of part 110 alone do not adequately address the unique characteristics of dietary supplements (72 FR 34752 at 34761). For example, unlike most foods, the majority of dietary supplements are packaged into tablets, gel caps, and capsules; some dietary supplements may contain bioactive ingredients for which specific, controlled amounts are intended to be in each tablet or capsule; vitamins can present a concentrated source of biologically active components that have adverse health consequences at high doses; and herbal and botanical dietary supplements are often complex mixtures that can vary in composition and be contaminated with substances having adverse health consequences depending on factors such as the part of the plant used, the location of harvesting and growing conditions that can vary from year-to-year (72 FR 34752 at 34761).

Part 111 includes those requirements of part 110 that are common to the manufacturing, packaging, labeling and holding of dietary supplements, such as requirements for personnel, physical plant and grounds, and equipment and utensils. Part 111 also establishes requirements such as for the use of written procedures for certain operations; a production and process control system that includes the establishment of specifications for incoming ingredients and finished product; certain requirements for testing of incoming ingredients and finished product; the establishment and implementation of quality control operations; the preparation and use of a written master manufacturing record for each unique formulation and for each batch size of a given dietary supplement; the preparation of an individual batch production record every time a dietary supplement batch is produced; the establishment and use of certain laboratory control processes; the investigation of any product

complaint that involves the possibility of a failure to meet any CGMP requirement; and the establishment and retention of records associated with the manufacture, packaging, labeling, or holding of a dietary supplement for specified periods of time.

g. Refrigeration of shell eggs held for retail distribution. In the **Federal Register** of December 5, 2000, FDA issued a final rule that established in § 115.50 (21 CFR 115.50) refrigeration requirements for shell eggs held for retail distribution (the shell egg refrigeration regulation) (65 FR 76092). FDA promulgated the shell egg refrigeration regulation to prevent foodborne illnesses and deaths resulting from the contamination of shell eggs with *Salmonella* Enteritidis (SE), a specific *Salmonella* serotype. As discussed in the proposed rule to establish the shell egg refrigeration regulation (64 FR 36492, July 6, 1999), the disease salmonellosis results from an intestinal infection with *Salmonella* microorganisms and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Most healthy people recover, but the infection can spread to the bloodstream, and then to other areas of the body, leading to severe and fatal illness, which is more likely to occur in children, the elderly, and persons with weakened immune systems. *Salmonella* spp. is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are the predominant source of SE related cases of salmonellosis in the United States where a food vehicle is identified for the illness (64 FR 36492 at 36493).

The shell egg refrigeration regulation requires that shell eggs held at retail establishments be stored and displayed under refrigeration at a temperature of 7.2 °C (45 °F) or less to help prevent the growth of *Salmonella* spp., except for shell eggs that have been specifically processed to destroy all viable *Salmonella* spp. that might be present. The shell egg refrigeration regulation includes administrative procedures with which refrigeration requirements may be enforced, including providing for the diversion or destruction of shell eggs that have been held in violation of the refrigeration requirements.

h. Production, storage, and transportation of shell eggs. In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued a final rule to establish in part 118 (21 CFR part 118) requirements for shell egg producers to register with FDA, implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and maintain records related to their compliance with the requirements of the regulation. As with the shell egg refrigeration rule, FDA promulgated part 118 to reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE (74 FR 33030).

3. Food Safety Guidance to Industry

FDA has issued numerous guidance documents (hereinafter, ''guidance'' or ''guidances'') to assist the food industry in implementing food safety regulatory requirements under FDA's jurisdiction. We issue guidances, in accordance with our regulations in § 10.115 (21 CFR 10.115) for ''good guidance practices,'' to describe our interpretation of or policy on a regulatory issue. Guidances do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA (§ 10.115(d)(1)). Accordingly, regulated industry is not required to employ the approaches contained in a guidance and instead may choose to use an alternative approach, provided that the alternative approach complies with the relevant statutes and regulations (§ 10.115(d)(2)). Although guidances do not legally bind FDA, they represent our current thinking on a particular interpretation of or policy regarding a given regulatory issue (§ 10.115(d)(3)). Under §§ 10.115(c)(1) and (g), we publish a guidance in draft form for public comment before issuing the guidance in final form, except where prior public participation is not feasible or appropriate, if the guidance (1) sets forth initial interpretations of statutory or regulatory requirements, (2) sets forth changes in interpretation or policy that are of more than a minor nature; (3) includes complex scientific issues, or (4) covers highly controversial issues.

FDA generally issues guidance to industry for the purpose of communicating our policy decisions and interpretations of our regulatory requirements so that regulated industry better understands how to comply with those requirements. In some cases, we issue guidance specifically targeted to assisting industry in complying with a particular food safety regulation. For example, we have issued guidances to assist industry in complying with the seafood HACCP regulation (Ref. 3) and the juice HACCP regulation (Ref. 4). In other cases, we issue guidance that is more narrowly focused in scope or is not directly targeted to assisting industry in complying with a particular food safety regulation. For example, we have issued guidance that addresses the chemical contamination of candy with lead (Ref. 5) and guidance on measures to address the risk for contamination by Salmonella spp. in food containing a peanut-derived product as an ingredient (Ref. 6).

4. Food Safety Compliance Policy Guides

FDA issues guidance to its staff in the form of compliance policy guides (CPGs). The primary purpose of a CPG is to explain FDA's policy on regulatory issues related to the statutes and regulations that we are responsible for implementing. CPGs advise FDA field inspection and compliance personnel as to FDA's standards and procedures to be applied when determining industry compliance with our regulatory requirements. FDA issues CPGs in accordance with our regulation for good guidance practices in § 10.115 and makes the CPGs available to the public, thereby providing regulated industry with additional insight into how we interpret the statutes and regulations we are responsible for implementing for purposes of assessing compliance with our regulatory requirements. In general, our food safety CPGs are relatively focused in scope. For example, we have issued a CPG regarding microbial contaminants in dairy products (Ref. 7 Ref. 7), and a CPG that sets forth the criteria that are to be used by FDA personnel to determine whether foods other than dairy products will be considered adulterated because of the presence of *Salmonella* spp. (Ref. 8).

5. Current Inspection System

Section 704 of the FD&C Act authorizes FDA to enter and inspect establishments in which food is manufactured, processed, packed, or held and to inspect all pertinent equipment, finished and unfinished materials, containers, and labeling located in such establishments (21 U.S.C. 374). We inspect food establishments both for cause, for example as part of foodborne illness outbreak investigations, and as a matter of routine practice. Section 421 of the FD&C Act (21 U.S.C. 350j), which was added to the FD&C Act by section 201 of FSMA, directs FDA to ''identify high risk-facilities and * * * allocate resources to inspect facilities according to the known safety risks of the facilities'' as determined by several factors, including among other things ''[t]he known safety risks of the food manufactured, processed, packed, or held at the facility'' and ''[t]he compliance history of a facility'' (Section 421(a)(1)). In addition, Section 421 requires FDA to: immediately ''increase the frequency of inspection of all facilities,'' and includes schedules

for the increased frequency with which ''domestic high-risk facilities,'' ''domestic non-high risk facilities,'' and ''foreign facilities'' must be inspected over time (Section 421(a)(2)). Section 421 also directs FDA to ''allocate resources to inspect any article of food imported into the United States according to the known safety risks of the article of food'' as determined by a number of factors, including among other things ''[t]he known safety risks of the countries or regions'' from which the food originates or through which it is transported, and ''[t]he compliance history of the importer'' (Section 421(b)).

FDA inspectors, or inspectors from other Federal agencies or the States authorized to conduct inspections on our behalf, inspect food establishments to determine whether the establishments are in compliance with the requirements of the FD&C Act and other applicable laws and regulations, and document their findings in Establishment Inspection Reports. Following an inspection, FDA may decide that: (1) No further action is required because no objectionable conditions or practices were found during the inspection; (2) voluntary action on the part of the food establishment is appropriate to correct violations that are serious enough to document but not serious enough to warrant a regulatory action, or (3) the practices and conditions discovered during the inspection are significant enough to require regulatory action by FDA (Ref. 9).

If we decide to initiate a regulatory action against a food establishment, we may elect to take an advisory action, such as issuing a Warning Letter, an Untitled Letter, or scheduling a regulatory meeting (Ref. 10). If we determine that the conditions and practices found at a food establishment constitute serious violations of the law that cannot be, or have not been, resolved by voluntary compliance, we may decide to initiate an administrative or judicial action, such as an administrative detention, an order to cease distribution and give notice under section 423(b) of the FD&C Act (21 U.S.C. 3501), a seizure of violative products, an injunction, or a criminal prosecution (Ref. 11) (Ref. 12).

6. Systems for Identifying Food Safety Problems

a. Contamination of food and foodborne illness. Food can become contaminated (e.g., with biological, chemical, physical, or radiological hazards) at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. As discussed more fully in section II.D of this document, consumption of contaminated food can lead to acute or long term illness or injury. Early detection of contamination enables food establishments to prevent contaminated food from entering commerce. When contamination is not detected in time to prevent contaminated food from entering commerce, the contamination may be detected while the food is in storage or in transit; at retail establishments; in restaurants; or in the home. This often necessitates a recall to retrieve the contaminated product from commerce.

We learn about contaminated food through a variety of mechanisms, including required reporting by industry; investigations of outbreaks of foodborne illness; recalls; and state surveillance and reporting programs. We discuss these mechanisms immediately below.

b. Required reporting by industry. In some cases, a firm that manufactures, processes, packs, or holds food, or a regulatory official, detects contamination of a food in the market. This may occur even when there is no known or suspected association between the food and reports of foodborne illness. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–085) established, among other things, section 417 of the FD&C Act (21 U.S.C. 350f), which requires FDA to establish a Reportable Food Registry (RFR). A ''reportable food'' is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals (Section 417(a)(2) of the FD&C Act). Under section 417(d)(1) of the FD&C Act, food firms that are ''responsible parties'' as defined in the statute are required to notify FDA electronically with certain information within 24 hours of determining that a food they manufactured, processed, packed, or held is a reportable food. On September 8, 2009, FDA launched the electronic portal for submission of these required reports. Information about reportable foods becomes part of the RFR.

Infant formula and dietary supplements are excluded from the requirements of the RFR. Infant formula manufacturers must comply with notification requirements for violative infant formula as established in 21 CFR 107.240. Manufacturers, packers and/or distributors whose names appear on the label of a dietary supplement marketed in the United States must submit to FDA any report received of a serious adverse event associated with that dietary supplement when used in the United States, accompanied by a copy of the dietary supplement's label, under section 761 of the FD&C Act (21 U.S.C. 379aa–1).

When contamination of food could cause illness or injury, quick action is necessary to remove the food from the market. FDA evaluates the information submitted to the RFR and that submitted by infant formula and dietary supplement firms and takes regulatory action when appropriate. Often this information can be used to determine the distribution of contaminated (and potentially contaminated) food, including raw agricultural commodities, food ingredients, and single- or multi-ingredient processed foods.

c. Outbreaks of foodborne illness. In some cases, contaminated food goes undetected until it is associated with an outbreak of foodborne illness. (An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) When an outbreak of foodborne illness occurs, quick action is critical to prevent additional illness. The CDC of HHS, and State, local, territorial and/or tribal health departments conduct epidemiologic investigations to identify the food(s) that may be involved in an outbreak. Many outbreaks are reported to the National Outbreak Reporting System (NORS) by the State, local, territorial, or tribal health department that conducted the outbreak investigation. Outbreak reporting is voluntary. Multi-state outbreaks are generally reported to NORS by CDC (Ref. 13). The Foodborne Outbreak Online Database (FOOD) allows the public direct access to information on foodborne outbreaks reported to CDC (Ref. 14).

In July 1995, the Foodborne Diseases Active Surveillance Network (FoodNet) was established as a collaborative program among CDC, 10 state health departments, USDA's Food Safety and Inspection Service (FSIS), and FDA. FoodNet conducts surveillance for infections caused by specific pathogenic microorganisms as diagnosed by laboratory testing of samples from patients. The surveillance area includes approximately 15 percent of the United States population (approximately 46 million persons). The objectives of FoodNet are to determine the burden of foodborne illness in the United States;

monitor trends in the burden of specific foodborne illness over time; attribute the burden of foodborne illness to specific foods and settings; and disseminate information that can lead to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness (Ref. 15). Information from FoodNet is used to assess the impact of food safety initiatives on the burden of foodborne illness (Ref. 16).

FDA works closely with CDC to monitor those outbreaks in which there is some indication or early information to suggest that an FDA regulated product may be implicated in an outbreak of foodborne illness. In some cases (e.g., when it appears unlikely that an implicated food was contaminated at the point of sale, such as at a restaurant), FDA works closely with multidisciplinary Federal, State, local, territorial, and tribal investigators during the investigation of the outbreak. Depending on the circumstances, such multidisciplinary investigations may involve a traceback investigation (i.e., an investigation to determine and document the production chain and the source(s) of contaminated or potentially contaminated food); a traceforward operation (i.e., an operation to determine the distribution of contaminated or potentially contaminated food); regulatory inspections; and, in some cases, root cause investigations (to try and determine the specific causes of contamination and contributing factors).

PulseNet is another collaborative program for the surveillance and detection of foodborne illness that is coordinated by the CDC, with laboratory participants from state health departments, local health departments, and Federal agencies, including FDA and FSIS. Using pulsed-field gel electrophoresis (PFGE), PulseNet participants perform standardized molecular subtyping (or fingerprinting) of foodborne disease causing bacteria. The patterns are then submitted electronically to PulseNet, which is a dynamic database that allows for the rapid comparison of patterns and facilitates identification of common source outbreaks. PulseNet is considered to be a powerful intelligence network that allows for the collection and analysis of state and local epidemiological surveillance data for the identification of outbreaks that may otherwise go unnoticed. In addition, PulseNet helps food regulatory agencies identify areas where the implementation of new measures and enhanced surveillance are likely to increase the safety of our food supply.

The Food Emergency Response Network (FERN) is a network coordinated by the FDA and USDA to integrate the nation's food testing laboratory (Ref. 17). The FERN supports all four phases of incident management—prevention, preparedness, response, and recovery—and coordinates the testing activities of Federal, state, and local laboratories. As of April 2011, FERN has 172 laboratory members (39 Federal, 116 State, and 17 local), located in all 50 States and Puerto Rico. FERN member laboratories represent the large majority of food testing laboratories in the U.S., including public health, agriculture, veterinary diagnostic and environmental laboratories. At this point, it is estimated that the FERN membership represents about 85% of all eligible food regulatory laboratories in the U.S.

FERN members use a web-based information network (the Electronic Laboratory Exchange Network, or eLEXNET) (Ref. 18) as their primary, real-time data exchange and communication system. Many participating laboratories conduct food surveillance testing programs for microbial pathogens (e.g., *E. coli* O157:H7, *Salmonella* spp., *Listeria monocytogenes,*), aflatoxin, antibiotics, undeclared allergens, heavy metals, and other threats to the food supply. Laboratory results can be uploaded into eLEXNET for the early identification of threats to the food supply. For example, overlaying laboratory results with distribution and epidemiological data can assist in identifying the source of the outbreak. The system also allows officials to analyze risks and identify trends for future surveillance efforts. In addition, the eLEXNET serves as a method repository for laboratories to rapidly search, access, review, and print methods.

d. Recalls. In 1978, we established a program regarding recalls, including guidance on policy, procedures, and industry responsibilities (43 FR 26202, June 16, 1978). Our regulations in part 7, subpart C (21 CFR part 7, subpart C) address recall policy; health hazard evaluation and recall classification; recall strategy; FDA-requested recall; firm-initiated recall; recall communications; public notification of recall; recall status reports; termination of a recall; and general industry guidance. In addition, under authority in section 412(f) of the FD&C Act (21 U.S.C. 350a(f)), we have issued regulations establishing specific requirements for infant formula recalls (21 CFR part 107, subpart E). More recently, FSMA amended the FD&C Act by establishing section 423 of the FD&C Act (21 U.S.C. 350l), which provides FDA with mandatory recall authority for food (other than infant formula, which remains subject to section 412(f) of the FD&C Act).

Section 7.41 (Health hazard evaluation and recall classification) describes how we evaluate the health hazard presented by a product being recalled by considering whether any disease or injuries have already occurred from the use of the product; whether any existing conditions could contribute to a clinical situation that could expose consumers to a health hazard; how the hazard could impact various segments of the population (e.g., children, surgical patients), with particular attention paid to the hazard to those individuals who may be at greatest risk; the degree of seriousness of the health hazard to which the populations at risk would be exposed; the likelihood of occurrence of the hazard; and the potential consequences (immediate or long-range) of occurrence of the hazard. On the basis of this evaluation, we classify the recall (i.e., Class I, Class II, or Class III) to indicate the relative degree of health hazard of the product being recalled or considered for recall. A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (§ 7.3(m)(1)). A Class II recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (§ 7.3(m)(2)). A Class III recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences (§ 7.3(m)(3)).

In recent years, recalls of food ingredients have highlighted the potentially large impact that contamination (or potential contamination) of a single food ingredient can have on thousands of food products containing that ingredient (Ref. 19) (Ref. 20) (Ref. 21) (Ref. 22) (Ref. 23) (Ref. 24), with correspondingly significant disruption and cost for industry and consumers.

e. State surveillance and reporting programs. State food safety agencies are involved in identifying contaminated food by conducting surveillance testing (Ref. 25). Communication of surveillance testing results by state food safety agencies to FDA is essential for identifying contaminated food. State food safety agencies also conduct thousands of inspections and collect and analyze food samples at food

manufacturers/processors every year under contract to FDA. The states perform inspections of food manufacturers, processors, packers and holders to determine compliance with the FD&C Act, state law, or both. Such inspections focus on identifying significant CGMP violations and insanitary conditions which may render the food injurious to health, particularly those involving the introduction of, lack of controls for, and/or growth promotion of pathogenic organisms. State inspections also focus on identifying practices or other conditions that may have caused food to become filthy, putrid, decomposed, or contaminated with foreign objects (Ref. 26). FDA coordinates eLEXNET), which is a web-based information network that allows state food safety officials to share laboratory analysis findings with FDA and other Federal, state and local food safety agencies (Ref. 18). FDA also participates in FERN, which is an FDA/FSIS joint initiative to integrate the nation's food-testing laboratories at the local, state, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food (Ref. 17).

7. Outreach to Consumers and Educators

As part of its efforts to protect the public health, FDA engages in outreach efforts to provide consumers and educators with information regarding the safe handling, preparation, and consumption of food to reduce the incidence of foodborne illness.

We conduct some of our consumer and educator outreach initiatives in cooperation with other Federal departments and agencies. For example, HHS, USDA, and their constituent agencies maintain the Internet site *FoodSafety.gov. FoodSafety.gov,* which provides consumers and health educators with the most current information regarding, among other things, food recalls and alerts, health risks posed by particular food safety hazards, instructions for the safe handling and preparation of food, and the most current news and information released by FDA and the other participating Federal departments and agencies regarding food safety issues (Ref. 27).

We also engage in consumer outreach in partnership with non-governmental entities. Most prominently, HHS, USDA, and the U.S. Department of Education work with industry associations, academic institutions, consumer and public health organizations, and professional societies in the food sciences to support the Partnership for Food Safety Education. This partnership, among other things, educates consumers about the importance of safe food handling and health risks posed by specific foodborne illnesses, prepares and disseminates food safety curricula for use by educators, and provides information regarding how consumers can be aware of and respond to food recalls (Ref. 28).

FDA also conducts its own independent informational outreach efforts specifically designed for consumers (Ref. 29) and for educators (Ref. 30).

B. FDA Food Safety Modernization Act

1. Requirements for Food Facilities

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418 with the same name. Many of the provisions in section 103 of FSMA that are relevant to this rulemaking are codified in section 418 of the FD&C Act.

a. General requirements. Section 418 of the FD&C Act contains requirements applicable to food facilities and mandates agency rulemaking. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to ''prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act] * * *.''

In addition to those areas specified in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' In section XII of this document, we discuss proposed requirements (proposed subpart C) that would implement these provisions of section 418 of the FD&C Act.

b. Qualified facilities. Section 418(l) of the FD&C Act (Modified Requirements for Qualified Facilities) establishes criteria for a facility to be a qualified facility, establishes an exemption for qualified facilities, establishes modified requirements for qualified facilities, and provides that the Secretary may withdraw the exemption otherwise granted to qualified facilities in specified circumstances. Under section 418(l)(1) of the FD&C Act, a facility is a qualified facility if (1) it is a very small business as the term would be defined by this rulemaking or (2) it falls within specified limitations on the average annual monetary value of its sales and types of customers. Section 418(l)(2)(A) of the FD&C Act exempts a qualified facility from the requirements for hazard analysis and risk-based preventive controls as set forth in sections 418(a)–(i) of the FD&C Act, as well as the requirements issued under section 418(n) of the FD&C Act. Section 418(l)(2)(B) of the FD&C Act requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws. Section 418(l)(3) of the FD&C Act authorizes the Secretary to withdraw the exemption from a qualified facility in specified circumstances. In section X.C.1 of this document, we discuss a proposed exemption for qualified facilities (proposed § 117.5(a)). In section XIV of this document, we discuss a proposed process for withdrawing an exemption for a qualified facility (proposed subpart E). In section XIII.A of this document, we discuss proposed modified requirements for qualified facilities (proposed § 117.201).

c. Exemptions and exceptions. In addition to the exemption for qualified facilities in section 418(l)(2)(A) of the FD&C Act, there are several other exemptions and exceptions to the requirements specified in section 418 of the FD&C Act. Section 418(j) of the FD&C Act provides an exemption for facilities that are required to comply and are in compliance with the regulations for seafood HACCP, juice HACCP, or thermally processed low-acid foods packed in hermetically sealed containers. Section 418(k) of the FD&C Act provides an exception for activities of facilities subject to section 419 of the FD&C Act (Standards for

Produce Safety). Section 103(g) of FSMA provides an exemption for certain activities regarding a dietary supplement that is in compliance with sections 402(g)(2) and 761 of the FD&C Act (21 U.S.C. 342(g)(2), 379aa–1). In sections X.C.2 through X.C.4 of this document, we discuss proposed exemptions for activities that are subject to part 123 (proposed § 117.5(b)), part 120 (proposed § 117.5(c)), part 113 (proposed § 117.5(d)), section 419 of the FD&C Act (proposed § 117.5(f)), or the manufacturing, processing, packing, and holding of dietary supplements (proposed § 117.5(e)).

As discussed in section II.B.2.e of this document, section 418(m) of the FD&C Act also authorizes the Secretary to create exemptions or modifications to the requirements with respect to certain facilities.

d. Rule of construction regarding alcohol-related facilities. As discussed in more detail in section X.C.7 of this document, section 116 of FSMA (21 U.S.C. 2206) (Alcohol-Related Facilities) provides a rule of construction for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages and other food. In section X.C.7 of this document, we discuss proposed exemptions related to such facilities (proposed § 117.5(i)).

2. Requirements for Agency Rulemaking

Section 103 of FSMA contains two separate rulemaking provisions. Section 103(a) of FSMA requires rulemaking related to the hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. In addition, section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of certain aspects of the definition of the term ''farm'' under section 415 of the FD&C Act (21 U.S.C. 350d) (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 of the FD&C Act (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) for certain facilities as the Secretary deems appropriate and as further specified in section 103(c)(1)(D) of FSMA.

a. General rulemaking requirements. Section 418(n)(1)(A) of the FD&C Act requires that not later than 18 months after the date of FSMA's enactment, the Secretary issue regulations ''to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls * * *.''

b. Definition of small and very small business. Section 418(l)(5) of the FD&C Act requires the Secretary, in consultation with the Secretary of Agriculture, to conduct a study of the food processing sector regulated by the Secretary and to make determinations in five areas. These areas include, in part, (1) distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food.

Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. These terms are significant because section 103 of FSMA contains several provisions specific to such entities.

- Small and very small businesses are subject to modifications or exemptions from requirements under section 418 or 421 of the FD&C Act for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (§ 103(c)(1)(D) of FSMA).
- Small and very small businesses are not subject to section 418 of the FD&C Act until 6 months (small businesses) or 18 months (very small businesses) after the effective date of FDA's final rule (§ 103(i) of FSMA).
- A very small business is deemed a ''qualified facility'' and would, therefore, qualify for the exemptions as discussed in section X.C.1 of this document. (§ 418(l)(1)(B) of the FD&C Act).

Consistent with section 418(l)(5) of the FD&C Act, FDA has consulted with USDA during its study of the food processing sector (Ref. 31). The study is available in the docket established for this proposed rule (Ref. 32). We request comment on that study. In section X.B.4 of this document, we discuss our proposed definitions for small business and very small business. We will consider comments regarding the study, as well as comments regarding our proposed definitions for small and very small business, in any final rule based on this proposed rule.

c. Clarification of the term ''facility.'' Generally, section 418 of the FD&C Act applies to the owner, operator, or agent in charge of a ''facility.'' Section 418(o)(2) of the FD&C Act defines ''facility'' as ''a domestic facility or a foreign facility that is required to register under section 415.'' Section 415 of the FD&C Act, in turn, requires any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States to register with the Secretary.

The requirement in section 415 of the FD&C Act that a facility must register does not apply to farms. FDA's implementing regulations for section 415 (see part 1, subpart H) (21 CFR part 1, subpart H; hereinafter the section 415 registration regulations) define ''farm,'' in relevant part, as ''a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both'' (§ 1.227(b)(3)) (21 CFR 1.227(b)(3)). The term ''farm'' includes a facility that packs or holds food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(i)). Under that same definition, the term ''farm'' also includes a facility that manufactures/processes food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(ii)).

Section 103(c)(1)(A) of FSMA requires that not later than 9 months after the date of enactment, the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations for purposes of section 415 of the FD&C Act with respect to ''activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership'' and ''activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.'' The regulation is intended to ''enhance the implementation'' of section 415 and ''clarify the activities that are included within the definition of the term 'facility' '' (§ 301(c)(1)(B) of FSMA). In section VIII.E of this document, we discuss our proposal to revise the section 415 registration regulations to enhance the implementation of section 415 and to clarify the definition of the term ''facility.''

d. Science-based risk analysis and requirements under sections 418 and 421 of the FD&C Act. Section 103(c)(1)(C) of FSMA requires that in issuing the proposed rule the Secretary conduct a science-based risk analysis of:

- ''Specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or

another farm under the same ownership, as such packing and holding relates to specific foods; and

• Specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.''

As part of the rulemaking, the Secretary is required to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 and 421 of the FD&C Act or modify those requirements, as the Secretary determines appropriate, if such facilities are only engaged in specific types of on-farm manufacturing, processing, packing, or holding activities the Secretary determines to be low risk, and involving specific foods that the Secretary determines to be low risk (§ 103(c)(1)(D)(i) of FSMA). Any exemption or modification is limited to small and very small businesses (§ 103(c)(1)(D)(ii) of FSMA).

In section VIII.G of this document, we discuss our approach to the requirement in FSMA section 103(c) for a science-based risk analysis of the types of on-farm manufacturing, processing, packing, or holding operations that can involve food that is not consumed on that farm or on another farm under common ownership for purposes of section 415 of the FD&C Act and request comment on that approach. The final approach will consider comments received to this proposed rule.

In sections VIII.I and X.C of this document, we discuss proposed exemptions for small and very small businesses that are solely engaged in certain types of ''low risk'' activities involving the on-farm manufacturing, processing, packing, and holding of certain ''low risk'' foods from the requirements of section 418 of the FD&C Act (proposed § 117.5(g) and (h)). In section VIII.J of this document, we discuss our tentative conclusion that we should not exempt or modify the frequency requirements under 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business and we seek comment on this proposal.

e. Exemption or modification of requirements for certain facilities. Under section 418(m) of the FD&C Act, the Secretary may exempt or modify the requirements for compliance of section 418 of the FD&C Act for hazard analysis and preventive controls for facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. As discussed in section X.C.8 of this document, in accordance with the discretionary language of section 418(m), FDA tentatively concludes that facilities solely engaged in the storage of RACs, other than fruits and vegetables, intended for further distribution or processing should be exempt from the requirements for hazard analysis and preventive controls that we are proposing to establish in subpart C of part 117.

Section 418(m) of the FD&C Act also authorizes the Secretary to exempt or modify the requirements for compliance with section 418 for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment. In section X.D of this document, we describe our proposal for how the requirements of part 117 would apply to such facilities (proposed § 117.7). In section X.D.4 of this document, we propose modified requirements for such facilities, directed at the storage of packaged foods that are not exposed to the environment and that require time/temperature control to limit the growth of, or toxin formation by, microorganisms of public health significance (proposed § 117.206).

f. Animal food and intentional adulteration. FDA proposes to implement section 103 of FSMA in several regulations, rather than a single regulation that covers all food and hazards subject to preventive controls. This proposal is applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds human food. Section 103 of FSMA applies to ''food,'' which is not limited to human food. Section 201(f) of the FD&C Act defines ''food'' to include ''articles used for food or drink for man or other animals'' (21 U.S.C. 321(f)). FDA tentatively concludes that the differences between human and animal food are best addressed through separate regulations. FDA plans to propose a separate regulation applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds animal food. Establishments that manufacture, process, pack, or hold food for both humans and animals should consider this proposed rule as well as the future proposed rule directed to CGMPs and hazard analysis and risk-based preventive controls for food for animals, as there may be differences in the requirements that would be applicable to such establishments under the two proposed rules.

In addition, this rulemaking is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism.'' (§ 418(b)(2) of the FD&C Act). FDA plans to implement section 103 of FSMA regarding such hazards in a separate rulemaking in the future. FDA tentatively concludes that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we also recognize that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. An example of this kind of hazard is the addition of melamine to certain food products apparently to enhance perceived quality and/or protein content. We request comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also request comment on when an economically motivated adulterant can be considered reasonably likely to occur.

C. Preventive Controls and Hazard Analysis and Critical Control Points (HACCP) Systems

1. HACCP Systems

HACCP is a preventive strategy for food safety that involves a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of hazards from a particular food or food production process or practice and the control of those hazards. HACCP has been endorsed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as an effective and rational means of ensuring food safety. NACMCF is an advisory committee chartered under USDA (Ref. 33). NACMCF includes participants from USDA's FSIS, HHS (FDA and CDC), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry, state employees and consumer groups. NACMCF provides guidance and recommendations to the Secretaries of USDA and HHS, as well as other Federal agencies, regarding the microbiological safety of foods. Although HACCP was first introduced in 1971 at the National Conference for Food Protection, it was not widely used by the food industry until the concept was more fully developed by NACMCF. In 1989 NACMCF adopted ''HACCP Principles for Food Production,'' which was revised in 1992; in 1997, NACMCF adopted its current version, ''Hazard Analysis and Critical Control Point

Principles and Application Guidelines'' (Ref. 34). Revisions in both the 1992 and 1997 NACMCF HACCP documents were patterned after changes made in HACCP documents issued by the Codex Alimentarius Commission (Codex). (The Codex Alimentarius Commission was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures as the international standards organization for food safety.) (See the discussion of Codex HACCP documents in section II.C.5.e of this document).

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption (Ref. 34). Under HACCP, a food operation develops a plan that identifies food hazards applicable to the food and production process, and the points in the production process where a food hazard could be introduced, controlled or enhanced. A failure at these points would likely result in a food hazard being created or allowed to persist. These points are referred to as critical control points (CCPs). Under HACCP, identified CCPs are systematically monitored to ensure that critical limits are not exceeded, and records are kept of that monitoring. Corrective actions are taken when control of a CCP is lost, including proper disposition of the food produced during that period, and these actions are documented. The effectiveness of HACCP is also systematically verified by the food operation.

2. Section 103 of FSMA and HACCP

FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. As discussed in section II.B of this document, section 103 of FSMA amended the FD&C Act by adding section 418. Section 418 of the FD&C Act and section 103 of FSMA are both titled ''Hazard Analysis and Risk-Based Preventive Controls.'' This title identifies two critical elements of HACCP—hazard analysis and preventive controls. As discussed in section II.C.4.a of this document, a hazard analysis is the first of the seven principles of HACCP, and is key to an effective food safety system. Further, establishment of a system of preventive controls for these hazards is the central purpose of HACCP. (See 66 FR 6138 and 60 FR 65096 stating that FDA issued the juice and seafood HACCP regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.) In addition, section 418(n)(5) of the FD&C Act requires that in promulgating the regulations to implement preventive controls, ''the Secretary shall review regulatory hazard analysis and preventive control programs in existence * * * to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards * * *.'' (See section XVI.B of this document for a discussion of this review.) The hazard analysis and preventive control systems in existence are all based on HACCP principles. Further, section 418 uses HACCP terminology throughout, including hazard analysis, monitoring, corrective actions, and verification. The close relationship of section 418 to HACCP is further illustrated by an exemption created in section 418(j) for ''seafood, juice, and low-acid canned food facilities subject to HACCP.''

At the same time, FDA notes that not every provision in section 418 of the FD&C Act is identical to HACCP as described in current literature. For example, as discussed in section II.C.4.b of this document, HACCP systems focus on determining CCPs, whereas section 418(c) requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, *including* at critical control points, *if any* (emphasis added). As another example, as discussed in section II.C.4.c of this document, HACCP systems focus on establishing critical limits for CCPs, whereas section 418(c) of the FD&C Act requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at CCPs, if any, without specifying that the preventive controls establish critical limits. In fact, section 418 of the FD&C Act does not use the term ''critical limit.'' Although the approach in section 418 and this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

As another example, as discussed in section II.C.4.a of this document, HACCP systems refer to hazards as ''biological, chemical and physical agents'' whereas section 418(b)(1)(A) of the FD&C Act requires that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including ''biological, chemical, physical, and *radiological* hazards'' (emphasis added). Although radiological hazards are not common, the consequences to consumers of exposure to radiological hazards may be severe (e.g., cancer). As discussed in section II.C.4.a of this document, under HACCP systems the hazard analysis includes a written assessment of the likelihood that the hazard will occur *and its severity* if it does occur (emphasis added). Thus, section 418(b)(1)(A) of the FD&C Act is consistent with the framework for HACCP even though it lists an additional type of hazard that must be considered and controlled as necessary.

Throughout this document, we identify the sections of FSMA applicable to specific proposed provisions and describe how the proposed provisions relate to HACCP principles as established by NACMCF in the NACMCF HACCP guidelines, by Federal agencies in HACCP regulations, and by Codex in the HACCP Annex in the Codex General Principles of Food Hygiene (Ref. 35).

3. Five Preliminary Tasks of HACCP/Preventive Controls

The NACMCF HACCP guidelines recommend a process for developing a HACCP system, or the implementation of a HACCP plan (Ref. 34). The ''five preliminary tasks'' of HACCP include: (1) Assembling a HACCP team; (2) describing the food and its distribution; (3) identifying the intended use and consumers of the food; (4) developing a flow diagram; and (5) verifying the flow diagram. The NACMCF HACCP guidelines advise that these preliminary tasks be accomplished before the application of HACCP principles to developing a HACCP plan for a specific food and process. Although FDA is not proposing to mandate that the owner, operator, or agent in charge of a facility conduct these preliminary tasks, facilities will greatly benefit from completing these preliminary tasks in developing their hazard analysis and risk-based preventive control systems.

4. The Seven Principles of HACCP

NACMCF has developed and adopted seven principles that describe the HACCP concept: (1) Conduct a hazard analysis; (2) Determine the CCPs; (3) Establish the critical limits; (4) Establish monitoring procedures; (5) Establish corrective actions; (6) Establish verification procedures; and (7) Establish recordkeeping and documentation procedures (Ref. 34). We discuss these immediately below.

a. Principle 1: Conduct a hazard analysis. The first HACCP principle is the identification of the hazards associated with the product and process. The NACMCF HACCP guidelines define a hazard as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (Ref. 34). The hazard analysis includes an identification of the hazard, an assessment of the likelihood that the hazard will occur and its severity if it does occur, and identification of control measures for each identified hazard, all of which should be documented.

b. Principle 2: Determine the CCPs. The second HACCP principle is identification of CCPs. The NACMCF HACCP guidelines define a CCP as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. 34). Steps in the manufacturing process that may be CCPs include heat treatment, chilling, product formulation, and metal detection.

c. Principle 3: Establish the critical limits. The third HACCP principle is establishing the critical limits, which involves establishing values for parameters that must be met for each control measure associated with a CCP. The NACMCF HACCP guidelines define a critical limit as a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard (Ref. 34). Critical limits can be thought of as boundaries of safety for each CCP (Codex defines a critical limit as a criterion which separates acceptability from unacceptability (Ref. 35)) and may be set for control measures such as temperature, time, physical dimensions, moisture level, water activity, pH, and available chlorine. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. For example, the minimum temperature and the minimum time at that temperature in a heat treatment step that will kill specific pathogens identified as hazards for a food are the critical limits for that CCP.

d. Principle 4: Establish monitoring procedures. The fourth HACCP principle is establishing monitoring procedures. The NACMCF HACCP guidelines define monitoring to mean conducting a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record of the monitoring for use in future verification procedures (Ref. 34). For example, monitoring can assess whether a CCP is operating within its critical limit. An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a deviation from a critical limit, monitoring procedures must be effective. Depending on the circumstances, monitoring may be on a continuous or a non-continuous basis. Continuous monitoring of a critical limit is possible with many types of physical and chemical methods. When it is not possible to monitor a critical limit on a continuous basis, monitoring intervals must be established that are frequent enough to determine whether the measure designed to control the hazard is consistently being met.

e. Principle 5: Establish corrective actions. The fifth HACCP principle is establishing corrective actions. The NACMCF HACCP guidelines define corrective actions as procedures followed when a deviation occurs (Ref. 34). While the HACCP system is intended to prevent deviations in a planned process from occurring, total prevention can rarely, if ever, be achieved. Therefore, procedures need to be in place to fix or correct the cause of the deviation to ensure that the CCP is brought under control, there is appropriate disposition of any food produced during a deviation, and records are made of the corrective actions taken. Out-of-control situations should be used to identify opportunities for improvement of the process to prevent future occurrences.

f. Principle 6: Establish verification procedures. The sixth HACCP principle is establishing verification procedures. The NACMCF HACCP guidelines define verification as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. 34). These activities may involve the application of methods, procedures, tests, and evaluations, other than monitoring. Verification activities, particularly those directed to validation, may be very scientific and technical in nature. For additional information about verification activities, see the discussion in section XII.G of this document. For additional information about the specific verification activity of ''validation,'' see the discussion in section XII.G.2 of this document.

g. Principle 7: Establish recordkeeping and documentation procedures. The seventh HACCP principle is establishing recordkeeping and documentation procedures. Written HACCP records list the hazards, CCPs, and critical limits identified by the facility, as well as the procedures that the facility intends to use to implement the system. Written HACCP records also include those generated during the operation of the HACCP system.

5. History of the Use of HACCP

a. HACCP regulation for fish and fishery products. In 1995, FDA issued a final rule to establish in part 123 procedures for the safe and sanitary processing and importing of fish and fishery products (60 FR 65096). Part 123 requires, among other things, that seafood processors apply HACCP principles to the processing of seafood. In the proposed rule to establish part 123, FDA identified several food safety hazards specific to the processing of fish and fishery products that warranted the promulgation of the seafood HACCP regulation, including microbiological hazards, naturally occurring toxins, chemical contaminants that might be present in the aquatic environment, and decomposition of fish and fishery products that might result from improper product handling and produce the toxin, histamine (59 FR 4142 at 4143–4144, January 28, 1994).

The HACCP regulation for seafood incorporated the seven HACCP principles as established in the 1992 revision of NACMCF's HACCP Principles for Food Production (''Hazard Analysis and Critical Control Point System'') (Ref. 36). The HACCP regulation for seafood also requires that individuals assigned the tasks of developing, reassessing, or modifying a HACCP plan, and conducting required records review must be adequately trained in the application of HACCP principles to fish and fishery products, evidenced either by the successful completion of the equivalent of a standardized curriculum recognized as adequate by FDA or by sufficiently adequate work experience (§ 123.10). The HACCP regulation for seafood does not require the use of NACMCF's five preliminary tasks as prerequisites to conducting a hazard analysis or developing a HACCP plan. We believe, however, that processors greatly benefit from using these preliminary steps in developing their HACCP systems (60 FR 65096 at 65117).

The HACCP regulation for seafood also requires that processors of seafood products monitor the conditions and practices of a sanitation standard operating procedure (SSOP); correct, in a timely manner, those conditions and practices that are not met; and document the monitoring and corrections (§ 123.11). In addition, the HACCP regulation for seafood is explicit that the general, umbrella CGMP

requirements for human food of part 110 apply to processors of fish and fishery products in determining whether the facilities, methods, practices, and controls used are safe, and whether the products have been processed under sanitary conditions (§ 123.5(a)).

In section XII of this document, we describe provisions of the HACCP regulation for seafood in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the HACCP regulation for seafood.

b. HACCP regulation for meat and poultry. In 1996, FSIS issued a final rule to establish in 9 CFR part 417 a regulation that, among other things, requires each meat and poultry establishment to develop and implement a system of HACCP controls designed to improve the safety of their products (61 FR 38806, July 25, 1996). In the remainder of this document, the phrase ''FSIS HACCP regulation for meat and poultry'' refers to 9 CFR part 417. FSIS issued its HACCP regulation for meat and poultry in light of outbreaks of foodborne illness and studies (conducted by the National Academy of Sciences, the U.S. General Accounting Office, and FSIS) that established the need for fundamental change in the FSIS meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of FSIS' resources (61 FR 38806 at 38807).

The FSIS HACCP regulation for meat and poultry incorporates the seven HACCP principles as established in the 1992 revision of NACMCF's HACCP Principles for Food Production (Ref. 36). Unlike our HACCP regulations for seafood and for juice, the FSIS HACCP regulation for meat and poultry requires two of the NACMCF preliminary tasks—i.e., that a flow chart describing the steps of each process and product flow in the establishment be prepared and that the intended use and consumers of the finished product be identified (9 CFR 417.2(a)(2)).

The FSIS HACCP regulation for meat and poultry requires the establishment to develop, implement and maintain written SSOPs that describe the procedures an establishment will conduct daily, before and during operations, to prevent direct contamination or adulteration of products (9 CFR 416.11 and 416.12(a)). Establishments must monitor the implementation of the SSOPs (9 CFR 416.13(c)), take appropriate corrective actions (9 CFR 416.15), and maintain records that document the implementation and monitoring of the SSOPs (9 CFR 416.16).

In section XII of this document, we describe provisions of the FSIS HACCP regulation for meat and poultry in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the FSIS HACCP regulation for meat and poultry.

c. HACCP regulation for juice. In 2001, FDA issued a final rule to establish in part 120 requirements to ensure the safe and sanitary processing and importation of fruit and vegetable juices for beverages (66 FR 6138). Part 120 requires, among other things, that processors of juice products apply HACCP principles to the processing of juice. We issued the juice HACCP regulation in light of a number of food safety hazards associated with juice products, including microbiological hazards that led to outbreaks of foodborne illness associated with juice products (63 FR 20449, at 20450–20451, April 24, 1998).

The HACCP regulation for juice incorporated the seven HACCP principles as established in the NACMCF HACCP guidelines adopted in 1997 and published in 1998 (Ref. 34). As with the HACCP regulation for seafood, the HACCP regulation for juice requires that individuals assigned the tasks of developing the hazard analysis, developing a HACCP plan, and verifying and modifying the HACCP plan must be adequately trained in the application of HACCP principles to juice products, evidenced either by the successful completion of the equivalent of a standardized curriculum recognized as adequate by FDA or by sufficiently adequate work experience (§ 120.13). As with the HACCP regulation for seafood, the HACCP regulation for juice does not require the use of NACMCF's five preliminary tasks as prerequisites to conducting a hazard analysis or developing a HACCP plan.

As with the HACCP regulation for seafood, the HACCP regulation for juice requires that processors of juice products monitor the conditions and practices of a sanitation standard operating procedure (SSOP); correct, in a timely manner, those conditions and practices that are not met; and document the monitoring and corrections (§ 120.6). In addition, the HACCP regulation for juice is explicit that the umbrella CGMP requirements of part 110 apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the juice products have been processed under sanitary conditions (§ 120.5).

Unlike the HACCP regulation for seafood, the HACCP regulation for juice, with certain exceptions, establishes requirements for process controls for pathogen reduction (§ 120.24). The HACCP regulation for juice also establishes requirements for process verification for juice processors, under certain circumstances, to analyze their finished juice products for the presence of *E. coli* using specified sampling and analytical methodologies (§ 120.25).

In section XII of this document, we describe provisions of the HACCP regulation for juice in more detail when we compare the proposed requirements for hazard analysis and risk-based preventive controls that are the subject of this document to provisions of current HACCP systems, including the HACCP regulation for juice.

d. Dairy HACCP pilot program. The Pasteurized Milk Ordinance (PMO) is a model milk regulation recommended by the U.S. Public Health Service/FDA for voluntary adoption by State and local milk control agencies. This model milk regulation includes provisions governing the processing, packaging and sale of Grade ''A'' milk and milk products and provides administrative and technical details on how to obtain satisfactory compliance. It is published to assist States and municipalities in initiating and maintaining effective programs for the prevention of milkborne disease. Currently all fifty states, the District of Columbia, and Puerto Rico have adopted the PMO by reference or have codified the PMO in state requirements. At its biennial conferences, the National Conference on Interstate Milk Shipments (NCIMS) considers changes and modifications to the Grade ''A'' PMO.

Appendix K of the PMO (the PMO HACCP Appendix) describes a voluntary, NCIMS HACCP Program alternative to the traditional inspection system. No milk plant, receiving station or transfer station may participate in the voluntary NCIMS HACCP Program unless the Regulatory Agency responsible for the oversight of the facility agrees to participate with the dairy plant(s), receiving station(s) and transfer station(s) in the NCIMS HACCP Program (Ref. 37).

The PMO HACCP Appendix incorporates the seven HACCP principles established in the 1998 NACMCF HACCP guidelines and essentially follows the same requirements as described in the HACCP regulation for juice (part 120).

SSOPs are referred to as ''required prerequisite programs (PPs).'' In contrast to the HACCP regulations for seafood and juice, the PMO HACCP Appendix requires that, in addition to the required PPs, any other PPs that the hazard analysis is relying upon to reduce the likelihood of hazards such that they would not be reasonably likely to occur also be monitored, audited, and documented. In this respect, the PMO HACCP Appendix is broader in scope than HACCP, in that it emphasizes the importance of monitoring, auditing, and documentation for the complete food safety system rather than focusing monitoring, auditing, and documentation solely on critical control points.

e. HACCP in the international food safety community. HACCP is recognized in the international food safety community as the state-of-the-art means to ensure the safety and integrity of food. In particular, the Committee on Food Hygiene of Codex has endorsed the HACCP concept as a worldwide guideline incorporated as an Annex into the Codex General Principles of Food Hygiene (GPFH) (Ref. 35). The European Union (EU) and other countries around the world have begun to require that foods be processed using a HACCP system. A discussion on the comparison of hazard analysis and preventive controls standards in section XVI.B includes those in Regulation (EC) No 852/2004 of the European Parliament and Council of the European Union Regulation (Ref. 38) (the EU Regulation), the Australia-New Zealand Food Standards Code (Ref. 39), and the Canadian Food Inspection Agency's Food Safety Enhancement Program (Ref. 40), all of which are based on the Codex HACCP Annex.

The HACCP reference documents from NACMCF and Codex have changed over the years as experience has been gained from the application of the concept in food production. These reference documents remain consistent with each other. This harmonization is critical, as these documents serve as the basis for hazard analysis and preventive controls standards internationally, thus providing for harmonized food safety standards among countries. Such harmonization facilitates trade by establishing a framework for ensuring safety. In addition to these standards serving as the basis for requirements by governments, there has been widespread international adoption of HACCP/preventive controls by industry at the company level, and as the foundation for food safety in third-party auditing schemes and certification efforts for companies, such as those benchmarked through the Global Food Safety Initiative (GFSI) (Ref. 41). (See section II of the Appendix to this document for more information on GFSI.)

The proposed rule would require that a food safety system similar to HACCP be implemented in food facilities and would harmonize our requirements with the recommendations and requirements of internationally recognized food safety experts/authorities, such as experts/authorities in NACMCF (Ref. 34), Codex (Ref. 35), FSANZ (Ref. 39), CFIA (Ref. 40), and the European Union (Ref. 38). The World Health Organization has recognized the importance of the HACCP system for prevention of foodborne diseases for more than 30 years and has played an important role in its development and promotion (Ref. 42). FAO likewise emphasizes the importance of HACCP and promotes it through international training and food safety manuals, e.g., for mycotoxin prevention and control (Ref. 43).

The Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), particularly the Agreement on the Application of Sanitary and Phytosanitary Measures (the ''SPS Agreement'') and the Agreement on Technical Barriers to Trade, had significant implications for Codex standards. Specifically, the SPS Agreement identifies Codex standards, guidelines and other recommendations as the baseline for consumer protection. As a result, the work of Codex (including the Codex HACCP Annex (Ref. 35) has become the reference for international food safety requirements. The Codex GPFH recommends a HACCP approach wherever possible to enhance food safety (Ref. 44). The international recognition of the HACCP approach as essential to ensuring the safety and suitability of food for human consumption enhances the potential for international trade as well as food safety (Ref. 43).

D. Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding of Food for Human Consumption

1. Contamination of Food

Food can become contaminated (e.g., with biological, chemical, physical, or radiological hazards) at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. Consumption of contaminated food can lead to acute or long term illness or injury. CDC estimates that each year approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths are food related (Ref. 45) (Ref. 46). These numbers include all illnesses that CDC estimates are attributable to food, including those illnesses caused by unspecified agents. These estimates also include a correction factor to account for the fact that foodborne illness is under-reported (Ref. 47). Focusing only on the foodborne illnesses attributable to particular pathogens, a recent CDC report estimated that consumption of food contaminated with pathogenic bacteria (such as *Campylobacter* spp., *Clostridium perfringens,* Shiga toxin-producing *Escherichia coli* (STEC) O157, STEC non-O157, *Listeria monocytogenes, Salmonella* spp., *Vibrio* species, *Yersinia enterocolitica*), parasites (such as *Cryptosporidium* spp. and *Giardia intestinalis*) and viruses (such as norovirus) cause more than 9 million episodes of foodborne illness, nearly 56,000 hospitalizations, and more than 1,300 deaths in the United States each year (Ref. 45). (A pathogenic microorganism is a microorganism capable of causing illness or injury.) Other food-related problems are caused by chemicals, allergens, and other harmful substances, such as glass (see sections II.D.2.b through II.D.2.d of this document for a discussion of these problems).

Early detection of contamination enables food establishments to prevent contaminated food from leaving their premises. When contamination is not detected in time to prevent contaminated food from leaving an establishment, the contamination may be detected while the food is in storage or in transit; at retail establishments; in restaurants; or in the home and often results in the need for a recall. Contamination after the food leaves the establishment may be detected during an investigation of an outbreak of foodborne illness or may be detected by end users (e.g., restaurants and consumers may identify physical hazards such as metal fragments or pieces of glass).

In recent years, we have taken a number of actions to prevent contamination of food at each step in the farm-to-table continuum. We have worked with other Federal, State, local, territorial, tribal, and foreign counterpart food safety agencies to strengthen the Nation's food safety systems across the entire distribution chain. This cooperative work has resulted in a greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new or better surveillance systems, and the ability to respond more quickly to

outbreaks of foodborne illness. (An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) However, changes in consumer preferences, changes in industry practices, and the rising volume of imports continue to pose significant challenges for FDA (72 FR 8750, February 27, 2007; 73 FR 55115, September 24, 2008). There are also many foodborne illnesses associated with unknown agents, which presents challenges in outbreak investigations (Ref. 46). In addition, microorganisms can change their characteristics by acquiring genes, including those for virulence, from other microorganisms (Ref. 48).

2. Microbiological, Chemical, Physical, and Radiological Hazards

In the following discussion of hazards, we highlight four categories: microbial, chemical (including allergens), physical, and radiological. Of the four types of hazards, there is far more information and data on microbiological problems associated with foods than with the others.

a. Microbiological hazards. Foodborne illness can have very serious consequences, including death. Below, we discuss several microorganisms commonly associated with foodborne illness.

Salmonella spp.

Salmonella contamination has been associated with eggs, milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, cocoa, and chocolate (Ref. 49). In a recent report tracking trends in foodborne illness, CDC reported that in 2010 *Salmonella* spp. was the most common foodborne pathogen and the most common cause of hospitalization and death (Ref. 50). The incidence of foodborne illness due to *Salmonella* spp. has not declined significantly in the last 15 years (Ref. 50). *Salmonella* spp. can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems (Ref. 49) (Ref. 51). Healthy persons infected with *Salmonella* spp. often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* spp. can result in the organism getting into the blood stream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis (Ref. 49) (Ref. 51).

Listeria Monocytogenes

Listeria monocytogenes is another pathogen often implicated in foodborne illness. In 2011, CDC reported that of all the foodborne pathogens tracked by CDC through FoodNet, *L. monocytogenes* had the highest case fatality rate (12.8 percent) and the highest hospitalization rate (89.6 percent) (Ref. 50). *L. monocytogenes* is a bacterium that occurs widely in both agricultural (soil, plants and water) and food processing environments. *L. monocytogenes* can multiply slowly at refrigeration temperatures, thereby challenging an important defense against foodborne pathogens—i.e., refrigeration (Ref. 52) (Ref. 53). Ingestion of *L. monocytogenes* can cause listeriosis, which can be a life-threatening human illness. Serious illness almost always occurs in people considered to be at higher risk, such as the elderly and those who have a preexisting illness that reduces the effectiveness of their immune system (Ref. 54). In addition, perinatal listeriosis results from foodborne exposure of the pregnant mother leading to in utero exposure of the fetus, resulting in fetal infection that leads to fetal death, premature birth, or neonatal illness and death. *L. monocytogenes* also causes listerial gastroenteritis, a syndrome typically associated with mild gastrointestinal symptoms in healthy individuals (Ref. 54) (Ref. 55).

The risk of illness from *L. monocytogenes* associated with a particular food is dependent on five key factors (Ref. 52) (Ref. 53):

- Amount and frequency of consumption of a food;
- Frequency and extent of contamination of a food with *L. monocytogenes;*
- Ability of the food to support the growth of *L. monocytogenes;*
- Temperature of refrigerated/chilled food storage; and
- Duration of refrigerated/chilled storage.

In 2003, FDA and FSIS, in consultation with CDC, released a quantitative assessment (the FDA/FSIS Lm RA) of relative risk associated with consumption of 23 categories of ready-to-eat (RTE) foods that had a history of contamination with *L. monocytogenes,* or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis (Ref. 53). The FDA/FSIS Lm RA shows that the risk of illness from *L. monocytogenes* increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of *L. monocytogenes* than from those that do not (Ref. 56). FAO/WHO released a risk assessment on *L. monocytogenes* in RTE foods in 2004. A key finding of that risk assessment was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. 54). Refrigerated foods present a greater risk from *L. monocytogenes* because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if *L. monocytogenes* is present in a food. Growth of *L. monocytogenes* does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with *L. monocytogenes* is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from *L. monocytogenes* in that food increases.

Escherichia Coli O157:H7

One of the most serious foodborne pathogens in terms of symptoms is *Escherichia coli* O157:H7, one of the enterohemorrhagic strains of *E. coli.* While the incidence of *E. coli* O157:H7 infection has been declining in recent years, it is still among the top five pathogens causing hospitalization as a result of foodborne illness (Ref. 45).

E. coli is a normal inhabitant of the intestines of all animals, including humans. However, *E. coli* O157:H7 is a rare variety of *E. coli* that, among other virulence factors, produces one or more related, potent toxins that cause severe damage to the lining of the intestine. Hemorrhagic colitis is the name of the acute disease caused by *E. coli* O157:H7. The illness is characterized by severe cramping (abdominal pain) and diarrhea, which often becomes bloody. Occasionally vomiting occurs. The illness is usually self-limited and lasts for an average of 8 days. Some victims, particularly the very young, develop hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia. From 0 to 15 percent of hemorrhagic colitis victims may develop HUS. The disease can lead to permanent loss of kidney function and death (Ref. 49).

Noroviruses

Noroviruses are a group of related, single-stranded RNA, non-enveloped viruses that cause acute gastroenteritis in humans. Norovirus is the official genus name for the group of viruses previously described as ''Norwalk-like viruses'' (NLV) or small round structured viruses (SRSVs) because of their morphologic features. Norovirus infection usually presents as acute-onset vomiting, watery non-bloody diarrhea

with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and diarrhea is more common than vomiting in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually last 24 to 72 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae (i.e., chronic conditions resulting from the illness) (Ref. 57). Noroviruses are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Noroviruses are highly contagious and as few as 10 viral particles may be sufficient to infect an individual. During outbreaks of norovirus gastroenteritis, more than one mode of transmission has been documented—e.g., initial foodborne transmission in a restaurant by a contaminated food, followed by secondary person-to-person transmission to household contacts. CDC recently estimated that there are 5.4 million cases of domestically-acquired foodborne illness each year due to norovirus infection, and more than 58 percent of all foodborne illnesses can be attributed to norovirus (Ref. 45).

As part of the work of the CGMP Working Group, FDA reviewed its food recall records for recall actions that were classified I or II for fiscal years 1999 through 2003 to identify those recalls that took place because of problems that could have been prevented by CGMP-type preventive measures such as proper equipment sanitation, adequate training of employees, review of product labels for accuracy and agreement with the product formulation, and adequate preventive maintenance of equipment (Ref. 58). The review did not include Class III recalls because these recalled products are not likely to have caused adverse health consequences. FDA repeated this type of review 5 years later, for the period 2008–2009 (Ref. 59). In these two reports, the second most common reason for such recalls was microbiological contamination (Ref. 58) (Ref. 59). Approximately 17 percent of such recalls during 1999–2003 and 24 percent of such recalls during 2008–2009 were linked to microbiological hazards. During 2008–2009, the two most commonly implicated pathogens in such recalls were *L. monocytogenes* (9.9 percent) and *Salmonella* spp. (7.6 percent). In the first annual report on the Reportable Food Registry, the three main pathogens associated with the 229 primary reports received by the RFR were *Salmonella* spp. (37.6 percent), *L. monocytogenes* (14.4 percent), and *E. coli* O157:H7 (2.6 percent) (Ref. 60). In the second annual report on the Reportable Food Registry, the three main pathogens associated with the 225 primary reports received by the RFR were Salmonella spp. (38.2 percent), *L. monocytogenes* (17.8 percent), and *E. coli* O157:H7 (0.4 percent) (Ref. 61).

There are many other pathogens associated with foodborne illness; however the four described above have been implicated in many recent outbreaks of foodborne illness as demonstrated by the examples below.

- In 2006–2007, a commercial brand peanut butter contaminated with *Salmonella enterica* serotype Tennessee (usually shortened to *Salmonella* Tennessee) caused 715 confirmed cases of illness, including 129 hospitalizations (Ref. 62). (*Salmonella* spp. are grouped into serotypes (also called serovars) based on cell surface antigens, which are determined by serologic testing. The serotype is often named after the location where it was isolated.) This was the first outbreak associated with peanut butter in the United States (Ref. 63). Investigators detected *Salmonella* spp. in environmental samples collected at the manufacturer's facility as well as in finished product (Ref. 64) (Ref. 65). Two years later, in 2008–2009, another large *Salmonella* outbreak was linked to peanut butter and peanut paste (Ref. 66) (Ref. 67). Implicated products included contaminated peanut butter consumed at institutional settings and peanut crackers made with the contaminated peanut butter as an ingredient (Ref. 66). This single outbreak resulted in 714 confirmed cases of illnesses, including 166 hospitalizations, and 9 deaths (Ref. 67). Inspections conducted by FDA at the manufacturing facilities revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 68) (Ref. 69).
- In 2007, a puffed snack food was implicated in a *Salmonella* Wandsworth and *Salmonella* Typhimurium outbreak. There were 87 confirmed reports of illnesses, including 8 hospitalizations. The likely source of contamination was a contaminated ingredient—i.e., imported dried vegetable powder that was applied to the puffed snack food after the cooking step (Ref. 51) (Ref. 70).
- From October 2008 to March 2009, a multistate *L. monocytogenes* outbreak was linked to Mexican-style cheese that was contaminated post-pasteurization. There were 8 confirmed cases of illness in 5 states (Ref. 71). An investigation at the plant revealed the potential for product contamination due to deficiencies in cleaning and plant and equipment maintenance (Ref. 72).
- In 2008–2009, white pepper was implicated in a *Salmonella* Rissen outbreak that resulted in a 87 confirmed cases of illness, including 8 hospitalizations and 1 death (Ref. 73) (Ref. 74). During the investigation, FDA isolated the outbreak strain from raw whole white pepper, in-process samples, finished products, and environmental samples taken at various locations throughout the processing areas (Ref. 75).
- In 2009, a prepackaged, refrigerated cookie dough was implicated in an *E. coli* O157:H7 outbreak that caused 76 confirmed cases of illness, including 35 hospitalizations (Ref. 76) (Ref. 77). *E. coli* O157:H7 was found in unopened packages of cookie dough in the production facility, although it was not the outbreak strain (Ref. 77) (Ref. 78).
- In 2011, an outbreak of listeriosis from cantaloupes was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (Ref. 79) (Ref. 80). The outbreak appears to have occurred due to a combination of factors, including pooled water on the floor of the facility (which was also difficult to clean), poorly designed equipment (not easily cleaned and sanitized) that was previously used for a different commodity, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 79).

b. Chemical hazards other than food allergens. There are a variety of ''chemical'' hazards that may be associated with food, including pesticide and drug residues, natural toxins, decomposition resulting in the production of toxins such as histamine, unapproved food or color additives, and food allergens. (We discuss food allergens in more detail in the next section of this document). Under the FD&C Act, certain products, such as food additives, color additives, new animal drugs, and pesticides require premarket approval before they may be legally used. (In the case of pesticides, EPA ''registers'' (i.e., approves) the use of pesticides and establishes tolerances (the maximum amounts of residues that are permitted in or on a food) if the use of a particular pesticide may result in residues in or on food. FDA enforces those tolerances, except for meat, poultry, and certain egg products, which are the responsibility of FSIS (Ref. 81).

Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding recognition that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested by a living animal before slaughter, how the product is metabolized in that animal.

Therefore, an additive, drug, or pesticide that has been approved for use in some foods, but not other foods, is deemed by the FD&C Act to be unsafe for use with those other foods. By specifically identifying pesticides, drug residues, and unapproved food and color additives as potential known or reasonably foreseeable hazards that a facility must consider and evaluate in its hazard analysis, section 418(b) of the FD&C Act emphasizes the current provisions of the FD&C Act regarding substances that require premarket review.

Natural toxins (such as aflatoxin in foods such as peanuts and tree nuts and patulin in apple juice products) are well recognized as hazards (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85). Decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. Biogenic amines other than histamine have been associated with illnesses, and these may also be formed when bacteria grow in some foods. Although certain fish species are the most common source of illness from histamine and other biogenic amines, illness from histamine has been reported from consumption of other foods, in particular cheese (Ref. 86) (Ref. 87). Heavy metals (such as lead) can lead to adverse health consequences (such as impaired cognitive development in children) (Ref. 88).

Depending on the particular chemical hazard and its level in the food, contamination of food with a chemical hazard may lead to immediate or near-term onset of illness (e.g., gastrointestinal illness), or may more commonly be associated with chronic exposure and long-term effects. Industrial chemicals (such as caustic cleaning compounds) can cause an acute reaction. Examples of long-term effects include impaired cognitive development in children exposed over time to relatively low levels of lead in contaminated candy (Ref. 88) and liver cancer as the result of chronic exposure to the mycotoxin aflatoxin (Ref. 89 (Ref. 90).

c. Chemical hazards—food allergens. Food allergies are immune-mediated adverse reactions to proteins. It has been estimated that food allergies affect four to six percent of children and two to three percent of adults (Ref. 91) (Ref. 92) (Ref. 93). A recent study by CDC estimates that approximately 3 million children in the United States (3.9 percent) have food allergies (Ref. 94). This study also reported that the prevalence of food allergies increased by 18 percent in this age group between 1997 and 2007 (Ref. 94).

The severity of a food allergic reaction varies depending on factors such as the amount of allergen ingested, the type of allergen, and the presence of other underlying medical conditions. Sensitive individuals may experience reactions to allergen doses as low as a few micrograms of food protein (Ref. 95) (Ref. 96) (Ref. 97). As high as one-third of sensitive individuals can experience severe reactions at the minimal eliciting dose of an allergen.

Allergic reactions from food result in an estimated 125,000 emergency room visits in the United States each year (Ref. 98), and as many as 100–150 deaths in the United States each year (Ref. 99) (Ref. 100). For children under 18 years of age, CDC estimates that there are approximately 9,500 food allergy-related hospitalizations per year (Ref. 101). The signs and symptoms associated with allergic reactions can range from oral irritation and swelling to cardiovascular collapse (Ref. 102).

Although more than 170 different foods have been reported to cause allergic reactions, most severe reactions are caused by the major food allergens defined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) (21 U.S.C. 321(qq)): milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. These eight allergens account for 90 percent of allergic reactions in affected individuals (Ref. 101). FALCPA amended the FD&C Act to prescribe the manner in which food labels must disclose that a food is, or contains an ingredient that bears or contains, a major food allergen (one of the eight listed above).

The most common CGMP related problem we have identified that resulted in a recall, both before and after FALCPA was passed, is labeling problems (i.e., undeclared allergen). In conjunction with the work of the CGMP Working Group, FDA reviewed CGMP-related food recalls during the period 1999–2003 (Ref. 58). Labeling problems accounted for 68 percent of food recalls, including 34 percent of recalls due to undeclared major food allergens. FDA followed up with a similar review of CGMP-related food recalls during the period 2008–2009, with a focus on primary recalls. (A primary recall is a recall initiated by a firm where the food safety problem first occurred. A subsequent recall is triggered by a primary recall. In a subsequent recall, the recalling firm is a recipient of an ingredient that is implicated in a primary recall.) In that follow-up review, labeling problems accounted for 62 percent of primary food recalls, including 43 percent of recalls due to undeclared major food allergens (Ref. 59). Thus, although FALCPA was passed in 2004, we continue to see problems with undeclared allergens in foods, as evidenced by recalls.

Some of the problems with undeclared allergens come to light only after consumers experience allergic reactions. For example, in August 2010, a prepared food with undeclared milk was recalled after a consumer complaint of an allergic reaction. It was discovered that the ''natural flavors'' used might have contained a milk product, but milk was not listed as an allergen on the product label (Ref. 103). In December 2010, a snack product with undeclared egg was recalled after a consumer complaint of an allergic reaction. The egg-containing product was mistakenly packaged in packaging designed for a similar product that did not contain egg (Ref. 104).

d. Physical hazards. Physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. Physical hazards may be associated with raw materials, especially raw agricultural commodities. The facility and equipment can also be a source of physical hazards, e.g., container glass and metal fragments such as nuts and bolts from equipment used in manufacturing/processing.

The first RFR Annual Report issued in January 2011 identified only three primary RFR entries for ''foreign objects'' (which were physical hazards that could have resulted in serious adverse health consequences or death), and all of these were in animal feed or pet food (Ref. 60). However, there have been recalls of human foods due to contamination or potential contamination with physical hazards. In October 2010, several types of frozen vegetables were recalled after shards of broken glass were found in some packages (Ref. 105) and in May 2011 several types of English muffins and bread products were recalled due to

possible contamination with small pieces of metal (Ref. 106).

e. Radiological hazards. Radiological contamination of foods is a rare event. Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium-235, uranium-238, plutonium-239, strontium-90, iodine-131, and cesium-137. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide to manufacture a food. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Ref. 107) (Ref. 108). Radiological hazards also may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In 2011, following the damage to a nuclear power plant during an earthquake and tsunami in Japan, radioactivity was subsequently detected in foods, particularly milk, vegetables, and seafood produced in areas neighboring the plant (Ref. 109).

Consuming food contaminated with radioactive material will increase the amount of radioactivity a person is exposed to, which could have adverse health effects. The health effect depends upon the radionuclide and the amount a person is exposed to. For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (Ref. 109).

f. Summary. As discussed above, food safety problems associated with microbiological, chemical, physical, and radiological hazards continue to cause illnesses and deaths and result in significant recalls. In its reviews of CGMP-related food recalls, FDA summarized key factors that contributed to the food safety problems that initiated the recalls. For recalls during 1999–2003, FDA concluded that the contributing factors (there could be more than one for a single recall) included incorrect packaging/labeling (68 percent), ineffective employee training (32 percent), failure to follow processing standard operation procedures (26 percent), excess/mistaken addition of chemicals/ingredients (9 percent), contamination of raw materials (8 percent), ineffective use of sanitation principles (8 percent), and unknown (4 percent). For recalls during 2008–2009, FDA used a slightly different methodology to categorize the contributing factors; the contributing factors included lack of label controls (57 percent), lack of supplier controls (37 percent), deficiencies in employee training (24 percent), lack of sanitation controls (17 percent), poor processing controls (13 percent), lack of environmental monitoring (9 percent), and unknown (1 percent). The findings from the two recall analyses demonstrate that over the past decade, similar types of food safety problems caused by similar types of contributing factors continue to challenge the food industry (Ref. 58) (Ref. 59).

3. Preventing Food Safety Problems

As discussed in section II.C of this document, HACCP is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur. The HACCP system aims to identify the points in the manufacturing process at which hazards might occur and to continuously monitor and control those points in an attempt to ensure that products meet pre-specified performance criteria (Ref. 34). The HACCP system is universally endorsed by international bodies such as Codex, the Food and Agriculture Organization, and the World Health Organization. During the last few years, HACCP systems have been mandated by U.S. Federal regulations established by FDA for seafood and juice, and established by FSIS for meat and poultry. (In the remainder of this document, we use the term ''Federal HACCP regulations'' to refer to these HACCP regulations for seafood, juice, and meat and poultry.) Codex has issued guidelines for HACCP systems (Ref. 35), and several industrialized nations or unions have mandated HACCP for part or all of their food industries (Ref. 38) (Ref. 39) (Ref. 40).

As discussed in sections II.C.1 through II.C.4 of this document, HACCP is a preventive system made up of interdependent activities including hazard analysis, preventive controls, monitoring, corrective actions, verification, and record keeping associated with these activities. These activities work together to prevent food safety problems; the individual activities, by themselves, are not as effective as the combination of these activities in the complete HACCP system. For example, a facility may determine that certain pathogens are reasonably likely to occur in a food product and establish and implement a heat treatment, for a specified combination of time and temperature, as a control to prevent the pathogens from contaminating finished food products. Unless the facility monitors the temperature and time during the heat treatment, the facility will not be able to determine whether its preventive control was, in fact, implemented. Moreover, the monitoring, by itself, would provide less value if the temperature was not documented during the monitoring and the documentation was not reviewed so that the facility can verify that the proper temperature was achieved for sufficient time. If the proper temperature or time is not achieved, corrective actions would be necessary to ensure that the food is reprocessed, diverted to a use that does not raise a food safety concern, or disposed. For the heat treatment to be effective, the level of any pathogens contaminating ingredients or other raw materials used to make the food must not exceed the level of pathogens that the heat treatment is validated to eliminate.

As discussed in section III of this document, FDA tentatively concludes that a modern food safety system based on HACCP principles can address the food safety problems discussed in sections II.D.1 through II.D.2 of this document.

E. The Role of Testing as a Verification Measure in a Food Safety System

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 34) (Ref. 110). Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. 111) (Ref. 112). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. As discussed in the Appendix to this document (see sections I.C, I.E, and I.F of the Appendix), microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;

• Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate RTE food; and

• Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the food.

Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. We discuss the role of testing as a verification measure in a food safety system in section I of the Appendix to this document.

F. The Role of Supplier Approval and Verification Programs in a Food Safety System

The development of a supplier approval and verification program can be part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients. We discuss supplier approval and verification programs in more detail in section II of the Appendix to this document.

III. Legal Authority

FDA is proposing changes to the Current Good Manufacturing Regulation under the FD&C Act and the Public Health Service Act. FDA is proposing changes to 21 CFR Part 1, Subparts H, I, and J under the FDA Food Safety Modernization Act and the FD&C Act. FDA is proposing all other new requirements under the FDA Food Safety Modernization Act, the FD&C Act and the Public Health Service Act.

A. Changes to Current 21 CFR Part 1, Subparts H, I, and J

Section 103(c)(1)(A) of FSMA requires that the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations for purposes of section 415 of the FD&C Act (Registration of Food Facilities) with respect to ''activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership'' and ''activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.'' In section VIII.E of this document, we discuss our proposal to revise the section 415 registration regulations (21 CFR subpart H) to clarify the types of activities that are included as part of the definition of the term ''facility'' under section 415 of the FD&C Act and the scope of the exemption for ''farms'' provided by section 415 of the FD&C Act. The proposed rule also would make corresponding changes in part 1, subpart I (Prior Notice of Imported Food) and in part 1, subpart J (Establishment, Maintenance, and Availability of Records). FDA's legal authority to modify these regulations is derived from section 103(c) of FSMA and 21 U.S.C. 414, 415, 381(m) and 371(a).

B. Changes to Current 21 CFR Part 110

FDA's legal authority to require Current Good Manufacturing Practices derives from sections 402(a)(3), (a)(4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3), 342(a)(4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The changes to the current CGMP regulation proposed in this document clarify the existing requirements of the regulation and update existing requirements to reflect changes in the food industry and in scientific understanding of food safety since issuance of the current regulation. In addition to the FD&C Act, FDA's legal authority for the proposed changes to current CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.)

C. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations ''to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls * * *.'' Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Further, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].''

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose

of the preventive controls is to ''prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act] * * *.'' In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include hazard analysis (§ 418(b)), preventive controls (§ 418(c)), monitoring (§ 418(d)), corrective actions (§ 418(e)), verification (§ 418(f)), recordkeeping (§ 418(g)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). In sections XII and XV of this document, we discuss proposed requirements (proposed subparts C and F) that would implement these provisions of section 418 of the FD&C Act.

Sections 418(j)–(m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to seafood and juice HACCP, and low-acid canned food (§ 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (§ 418(k)); qualified facilities (§ 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (§ 418(m)); facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (§ 103(c)(1)(D) of FSMA), and dietary supplements (§ 103(g) of FSMA). In sections X.C, XIII, and XIV of this document, we discuss proposed provisions (proposed § 117.5(a)–(j), and proposed subparts D and E) that would implement these provisions of section 418 of the FD&C Act and section 103 of FSMA.

FDA tentatively concludes that the provisions in subpart C and related requirements in subparts A, D, and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of Section 418 of the FD&C Act applies to facilities that are required to register under section 415 (§ 418(o)(2) of the FD&C Act) and does not exclude a facility because food from such a facility is not in interstate commerce. Section 301(uu) of the FD&C Act provides that ''the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418'', or the causing thereof, is a prohibited act.

FDA also is proposing the provisions in subpart C and related requirements in Subparts A, D, and F, under sections 402(a)(3), 402(a)(4), 403(w), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food; and to the extent necessary to prevent food from being misbranded under section 403(w). FDA is also proposing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent those provisions are necessary to prevent the interstate spread of communicable disease. FDA tentatively concludes that a modern food safety system based on HACCP principles can address the food safety problems discussed in section II.D of this document. The food safety system that we are proposing would require a facility to conduct a hazard analysis to determine those hazards that are reasonably likely to occur and establish and implement preventive controls for those hazards. To ensure that controls are properly implemented and effectively controlling the hazards, the proposed food safety system would establish requirements for monitoring, corrective actions, and verification, including validation that the preventive controls are adequate to control the identified hazards. Certain activities would be required to be conducted (or overseen) by a qualified individual and certain activities would be required to be documented. A written food safety plan would include the hazard analysis, the preventive controls that would be established and implemented to address those hazards determined to be reasonably likely to occur, procedures for monitoring, corrective actions, and verification, and a recall plan. The written plan and other documentation would be required to be made promptly available to FDA upon oral or written request.

FDA tentatively concludes that, taken as a whole, the food safety system described here is necessary to help prevent food safety problems associated with microbiological, chemical, physical, and radiological hazards in foods. Therefore, the proposed system is necessary to prevent food from being adulterated because it is unfit for food or because it has been held under insanitary conditions whereby it may become contaminated with filth or may be rendered injurious to health; to prevent food from becoming misbranded under section 403(w) of the FD&C Act; and to prevent the spread of communicable disease.

IV. Public Meeting and Preliminary Stakeholder Comments

A. Introduction

On April 20, 2011, FDA held a public meeting entitled ''FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities'' (**Federal Register** of April 13, 2011, 71 FR 20588). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FD&C Act. Although the meeting included introductory presentations by FDA, the primary purpose of the meeting was to listen to our stakeholders. In order to meet that goal, FDA provided multiple opportunities for individuals to express their views, including by providing opportunities for individuals to make presentations at the meeting during an open public and webcast comment session, whereby participants could make presentations in person or via webcast, and during another listening session that was held at the end of the day. Various stakeholders made presentations during these public sessions, including presentations made by representatives from consumer groups, industry trade associations, food companies, and state agencies. The major topics discussed in these comments included food allergens and the importance of allergen controls, verification and the importance of testing, submission of food safety plans to FDA, education and training on preventive controls, the need for flexibility in the regulations, modified requirements for certain packaged food items not exposed to the environment, on-farm manufacturing, processing, packing and holding activities, and states partnering with FDA to conduct inspections.

Stakeholders were given additional opportunities to express their views during break-out sessions focused on specific topics. Topics for the break-out sessions included preventive controls guidance, on-farm manufacturing and small business, preventive controls and the relationship to CGMPs, product testing and environmental monitoring, and training and technical assistance. A transcript of FDA's remarks at the opening session, the open public and

webcast comment session, and the listening session is available on FDA's Web site (Ref. 113). In addition, webcast videos were prepared for the public meeting and subsequently provided on FDA's Web site, including webcast videos of the opening session, open public comment session, listening session, and several breakout sessions (Ref. 114).

The notice announcing the public meeting also requested written comments. In response to this request, FDA received 30 written comment letters. The major issues presented in the written comment letters included the following: allergen control, accredited laboratories, environmental monitoring and product testing, flexibility of regulations and guidance, food defense, guidance and outreach, preventive controls, small businesses and exempted facilities, submission of the food safety plans to FDA, and modified requirements for warehouses. In the remainder of this section, we summarize each of the major issues raised in the written comments and identify the key proposed provisions applicable to the comments.

B. Comments on Allergen Control

Comments state that FDA should address the evaluation of allergens as a food hazard and the need for preventive controls for allergens in its implementation of section 418 of the FD&C Act. One comment notes that an effective allergen control plan is critical to protecting the health and confidence of consumers. Comments recommend that any required allergen control programs be limited to ''major food allergens,'' as defined in the FD&C Act.

We propose a definition of ''food allergen'' (proposed § 117.3) in section X.B.4 of this document and discuss proposed requirements for preventive controls directed to food allergens (proposed § 117.135(d)(2)) in section XII.C.6 of this document.

C. Comments on Accredited Laboratories

Several comments urge FDA to require use of accredited laboratories only when there is a known or suspected food safety problem and not in the routine course of business (testing raw/ingredient, in-process, or finished product). Some comments state it would be inconsistent with its statutory authority for FDA to require use of accredited laboratories beyond limited ''for cause'' circumstances, e.g., testing for ''identified or suspected food safety problems'' or imports.

Section 202 of FSMA creates a new section 422 in the FD&C Act addressing laboratory accreditation for the analyses of foods, including use of accredited laboratories in certain circumstances. This document does not propose additional requirements for the use of accredited laboratories and does not include a discussion of section 422 of the FD&C Act.

D. Comments on Environmental Monitoring and Product Testing

Many comments assert that the role and need for product testing and environmental monitoring varies depending on the type of products and processing operation and that it should be the facility's responsibility to determine the testing needed to verify that its preventive controls are effective. Others state that environmental and product testing may be appropriate in certain instances as verification activities, but they do not constitute a control step. A number of comments assert that finished product testing is extremely costly and cannot establish safety. As such, they recommend that industry and FDA should focus on ensuring that preventive measures are properly designated and effective instead of relying on finished product testing. One comment mentions that effective testing programs use aggressive and robust environmental testing and recognize the limited value of finished product testing. A few comments point out that finished product testing is particularly important for RTE products, and others suggest that environmental monitoring should be required only in the part of the facility that handles exposed RTE product. Some comments maintain that FDA should require verification testing when any food has an identified hazard for which a facility has implemented a preventive control, and others state that high-risk plants should be required to do microbial sampling to a standard and frequency set by FDA. A few comments encourage FDA to require plants to conduct both environmental sampling and testing of finished products to provide assurances that product coming off the end of the line has been produced in accordance with the plant's preventive control plan.

Section I in the Appendix to this document discusses a number of issues associated with environmental monitoring and product testing. Although we are not including provisions for environmental monitoring or product testing in this proposed rule, in section XII.J of this document, we request comment on these issues.

E. Comments on Flexibility of Regulations and Guidance

The majority of comments addressing this topic state that regulations and guidance should be science and risk-based, non-prescriptive, and flexible because of the wide variety of facilities that will be subject to the regulations. One notes that regulations should not require companies to hire outside consultants either explicitly or in practical terms because of their complexity.

As discussed in section XVI.A of this document, section 418(n)(3) of the FD&C Act requires that the content of the regulations promulgated under § 418(n)(1) of the FD&C Act provide sufficient flexibility to be practicable for all sizes and types of facilities; comply with chapter 35 of title 44, United States code (commonly known as the ''Paperwork Reduction Act''); acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls. Section XVI.A of this document also addresses how this proposed rule complies with the requirements in section 418(n)(3) of the FD&C Act.

F. Comments on Food Defense

Numerous comments reiterate the need for food defense to be treated distinctly from food safety, because they address separate issues and often involve different types of expertise within companies. They recommend that FDA allow manufacturers to develop and maintain two distinct sets of documents on these separate issues. One comment suggests that FDA consider implementing the food and feed defense-related provisions of FSMA through guidance, rather than regulation.

FDA discusses its tentative decision not to address ''hazards that may be intentionally introduced, including by acts of terrorism'' in section II.B.2.f of this document. As stated there, FDA plans to implement section 103 regarding such hazards in a separate rulemaking in the future.

G. Comments on Guidance and Outreach

Comments urge FDA to focus on education and outreach for farms, facilities, distributors, inspectors, and state departments of agriculture. They support guidance that would include information on conducting valid hazard analyses and risk assessments,

implementing preventive controls, and what constitutes a valid food safety plan. They also support guidance that would provide access to background resources, such as scientific studies, risk analyses and risk-based modeling. They state that guidance should include examples of food safety plans, both acceptable and unacceptable ones. One comment envisions several different types of guidance: how to identify hazards and how to distinguish preventive controls associated with HACCP plans from those falling outside HACCP plans; preventive controls that should be considered for certain categories of food (e.g., high risk food); and what constitutes a hazard and how you determine its likely occurrence.

Section 103(b) of FSMA requires FDA to issue a guidance document related to the ''regulations promulgated under subsection (b)(1) with respect to the hazard analysis and preventive controls under section 418'' of the FD&C Act. In addition, section 103(d) of FSMA requires, within 180 days after the issuance of the regulations, that FDA issue a small entity compliance policy guide setting forth in plain language the requirements of the regulations established under section 418(n) of the FD&C Act and section 103 of FSMA to assist small entities in complying with the hazard analysis and other activities required under section 418 of the FD&C Act and section 103 of FSMA. On May 23, 2011, FDA published a **Federal Register** notice announcing the opening of a docket [Docket No. FDA–2011–N–0238] to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes (76 FR 29767). FDA established this docket to provide an opportunity for interested parties to provide information and share views that will inform the development of guidance on preventive controls for food facilities that manufacture, process, pack, or hold human food. FDA anticipates issuing these required guidance documents in a timely manner in coordination with issuing the final regulations to assist our stakeholders in complying with the regulations.

FDA did not conduct HACCP training for persons subject to our HACCP regulations for seafood or juice. However, when implementing those regulations, FDA worked with an alliance of representatives from Federal and State agencies, industry and academia, to create a uniform, core training program that serves as the standardized curriculum against which other course materials can be judged. FDA will be working with an alliance to develop such a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls.

H. Comments on Preventive Controls

A number of comments point out that not all preventive controls need to be constructed as critical control points. Some urge FDA to work with each industry segment to develop a set of general preventive controls for that segment or to use existing preventive controls programs that may already exist for a segment of industry; those general preventive controls would be tailored to each situation, plant design, and product. One comment asserts that preventive controls must consider incoming water as a key risk and states that the risk assessment must be informed by current standards and methodologies and take into account resistance to traditional disinfectants.

FDA is proposing requirements for preventive controls in proposed § 117.135 (discussed in section XII.C of this document).

I. Comments on Small and Very Small Businesses

Several comments urge FDA to define a very small business. Many recommend that these businesses should be significantly smaller than those that gross $500,000 a year. One comment proposes that FDA define very small business as having fewer than 20 employees, stating that the Small Business Administration has done so. Another suggests that ''very small'' business be defined by the volume of product that they put into commerce. For facilities that satisfy criteria for the ''qualified facility'' exemption and therefore have the option of submitting documentation related to preventive controls or compliance with State, local, county, or other applicable non-Federal food safety law, several comments urge FDA to require that such facilities submit documentation of one option or the other. One comment disagrees that small processors should be exempt, since small processors frequently pose a risk to the public precisely because of their lack of sophistication and availability of trained technical staff.

We discuss our proposed definitions for small and very small businesses (proposed § 117.3) in section X.B.4 of this document. We discuss our proposed definition for ''qualified facility'' (proposed § 117.3) in section X.B.4 of this document; our proposed exemption from subpart C for a ''qualified facility'' (proposed § 117.5(a)) in section X.C.1 of this document; proposed modified requirements for a ''qualified facility'' (proposed § 117.201) in section XIII.A of this document; and a proposed process that would govern withdrawal of an exemption from subpart C for a ''qualified facility'' (proposed Subpart E) in section XIV of this document.

J. Comments on Submission of Food Safety Plan to FDA

Most comments agree that FDA should not require electronic submission of food safety plans, pointing out that not only would it be impractical, but also that food safety plans are most appropriately reviewed by FDA during on-site facility inspections, with the support of people familiar with the system who can answer questions and show an inspector relevant equipment, operations, and procedures. They note that plans are of limited utility outside of the plant context. However, a few comments state that FDA should request all initial food safety plans, as this would give us an idea of any misunderstandings of the preventive control requirements. These comments also note that submission of plans could help FDA quickly determine if high-risk facilities are developing effective plans and might help FDA prioritize inspections.

FDA is not proposing to require submission of food safety plans. We discuss this topic and request comment on alternate approaches in section XII.K of this document.

K. Comments on Modified Requirements for Warehouses

All comments submitted on the issue of warehouses urge FDA to modify the preventive controls requirements for facilities, such as warehouses, that are solely engaged in the storage of packaged foods that are not exposed to the environment, since no manufacturing or processing takes place at such food warehouses and the product is not exposed to the environment. Most state that the facility should have procedures in place addressing general controls, such as sanitation, pest control, storage, segregation, security, and recordkeeping.

FDA is proposing modified requirements for warehouses solely engaged in the storage of packaged food that is not exposed to the environment in proposed § 117.7 (discussed in section X.D of this document) and proposed § 117.206 (discussed in section XIII.B of this document).

V. Placement of Regulatory Requirements

We are proposing to establish the revised umbrella CGMP requirements, together with the new requirements for hazard analysis and risk-based preventive controls, in proposed part 117. As discussed in section XVII of this document, we are proposing to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117.

VI. Highlights of the Proposed Rule

A. Overview

The proposed rule would revise FDA's current regulations in part 110 regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it would add new provisions to implement section 103 of FSMA. Second, it would update, revise, or otherwise clarify certain requirements of our current regulations in part 110. The new provisions and revisions to the current CGMP requirements would be established in part 117. Under the proposed rule, new part 117 would be divided into the following subparts:

- Subpart A—General Provisions;
- Subpart B—Current Good Manufacturing Practice;
- Subpart C—Hazard Analysis and Risk-Based Preventive Controls;
- Subpart D—Modified Requirements;
- Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility; and
- Subpart F—Requirements Applying to Records That Must Be Established and Maintained.
- Subpart G would be reserved.

In the remainder of this section, we highlight key provisions of the proposed rule.

B. Proposed Revisions to 21 CFR Part 1, Subparts H, I, and J

To implement section 103(c) of FSMA, the proposed rule would revise certain definitions in FDA's current section 415 registration regulations. These revisions would clarify the types of activities that are included as part of the definition of the term ''facility'' under section 415 of the FD&C Act and the scope of the exemption for ''farms'' provided by section 415 of the FD&C Act. The proposed rule also would make corresponding changes in part 1, subpart I (Prior Notice of Imported Food) and in part 1, subpart J (Establishment, Maintenance, and Availability of Records).

C. Proposed Revisions to General Provisions of 21 CFR Part 110 (Part 110) (Proposed Part 117, Subpart A)

The proposed rule would both revise current provisions of subpart A of part 110 and add new provisions to subpart A as it would be established in proposed part 117. The new provisions would include specified exemptions for certain facilities, or for certain activities conducted by facilities, from the proposed requirements for hazard analysis and preventive controls in proposed part 117, subpart C. The proposed exemptions would be consistent with requirements established by FSMA or discretion provided by FSMA. The subjects of the specified exemptions relate to:

- A ''qualified'' facility;
- Activities subject to our existing HACCP regulations for seafood and juice, our regulations governing microbiological hazards in low acid canned foods, and our dietary supplement CGMP regulations;
- Activities of a facility that are subject to the Standards for Produce Safety in section 419 of the FD&C Act;
- Certain low-risk packing or holding activity/food combinations conducted on a farm by a small or very small business;
- Certain low-risk manufacturing/processing activity/food combinations conducted on a farm by a small or very small business;
- The receipt, manufacturing, processing, packing, holding, and distribution of alcoholic beverages and other prepackaged food sold in conjunction with alcoholic beverages (e.g., gift baskets);
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing; and
- Facilities solely engaged in the storage of packaged food that is not exposed to the environment, although the storage of such food that requires time/temperature control to prevent the growth of, or toxin formation by, pathogenic microorganisms would be subject to modified requirements that would be established in proposed subpart D.

D. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)

In order to modernize current CGMP requirements, the proposed rule would make revisions including:

- Modernizing and updating the language throughout (e.g., by replacing the word ''shall'' with the word ''must'' and by using certain terms consistently throughout proposed part 117);
- Deleting certain provisions containing recommendations, including the specific temperatures for maintaining refrigerated, frozen or hot foods;
- Clarifying that certain CGMP provisions requiring protection against contamination require protection against cross-contact of food as well to address allergens; and
- Proposing that provisions directed to preventing contamination of food and food-contact substances be directed to preventing contamination of food-packaging materials as well.

E. Proposed New Requirements for Hazard Analysis and Risk-Based Preventive Controls (Proposed Part 117, Subpart C)

1. Written Food Safety Plan

We propose to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes as applicable:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective action procedures;
- Verification procedures; and
- A recall plan.

2. Written Hazard Analysis

We propose to require that the written hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur, including biological, chemical, physical, and radiological hazards. The hazard analysis would include an evaluation of the identified hazards to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

3. Written Preventive Controls

We propose to require that the owner, operator, or agent in charge of a facility identify and implement preventive controls (including at critical control points, if any) to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented and that the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The preventive controls would include, as appropriate:

- Parameters associated with the control of the hazard and the maximum or minimum value, or combination of

values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur;

- Process controls;
- Food allergen controls;
- Sanitation controls;
- A recall plan; and
- Any other necessary controls.

4. Written Recall Plan

We propose to require that the written recall plan be developed for food with hazards that are reasonably likely to occur.

5. Monitoring

We propose to require the monitoring of the preventive controls to provide assurance that they are consistently performed, including requirements to establish and implement written monitoring procedures and establish and maintain records documenting the implementation of the monitoring procedures.

6. Corrective Actions

We propose to require that facilities establish and implement written corrective action procedures that would be used if preventive controls are not properly implemented and take corrective actions in the event of an unanticipated problem.

7. Verification

We propose to require that facilities conduct certain verification activities, including:

- Validation of a subset of the preventive controls;
- Verification that monitoring is being conducted;
- Verification that appropriate decisions about corrective actions are being made; and
- Verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.

We also propose to require reanalysis of the food safety plan at least once every 3 years and more often when circumstances warrant.

8. Qualified Individual

We propose to establish qualification requirements for a ''qualified individual,'' who would be required to do or oversee the preparation of the food safety plan, validation of preventive controls, review of records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and reanalysis of a food safety plan. A ''qualified individual'' would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

9. List of Required Records

We propose to establish a list of records that would be required under proposed subpart C, including the written food safety plan and records documenting monitoring of preventive controls, corrective actions, verification, and applicable training for the qualified individual.

F. Proposed New Provisions for Modified Requirements (Proposed Part 117, Subpart D)

Proposed subpart D would implement certain provisions in sections 418(l) and (m) of the FD&C Act for modified requirements with respect to:

- Qualified facilities: Implementing the modified requirements specified in section 418(l) of the FD&C Act for facilities that satisfy the statutory criteria for a ''qualified facility,'' we propose to establish requirements that include:
- Submission to FDA of documentation that the facility is a qualified facility; and
- Submission to FDA of documentation demonstrating that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or
- Submission to FDA of documentation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.
- Facilities solely engaged in the storage of packaged food that is not exposed to the environment: Acting on the discretion provided to FDA by section 418(m) of the FD&C Act, we propose to require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment conduct certain activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance, including:
- Establishing and implementing temperature controls;
- Monitoring the temperature controls;
- Taking appropriate corrective actions when there is a problem with temperature controls;
- Verifying that temperature controls are consistently implemented; and
- Establishing and maintaining the following records:
- Records documenting the monitoring of temperature controls;
- Records of corrective actions; and
- Records documenting verification activities.

We seek comment on these proposed requirements.

G. Proposed New Provisions for Withdrawal of an Exemption Applicable to a Qualified Facility (Proposed Part 117, Subpart E)

Proposed subpart E would implement the provisions of section 418(l)(3) of the FD&C Act and establish the conditions under which an exemption granted to a ''qualified facility'' could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

H. Proposed New Recordkeeping Requirements (Proposed Part 117, Subpart F)

Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 117, including:

- General requirements related to the content and form of records;
- Additional requirements specific to the food safety plan;
- Requirements for record retention;
- Requirements for official review of records by FDA; and
- Public disclosure.

VII. Compliance Dates

Section 103(i)(1) of FSMA, General Rule, provides that ''[t]he amendments made by this section shall take effect 18 months after the date of enactment'' (i.e., by July 4, 2012). Section 103(i)(2) of FSMA, Flexibility for Small Businesses, provides that ''[n]otwithstanding paragraph (1),'' the amendments made by this section ''shall apply'' to a small business and very small business beginning on the dates that are 6 months and 18 months, respectively, ''after the effective date'' of FDA's final regulation.

FDA is implementing the amendments made by section 103 to the FD&C Act through this rulemaking

(except as relates to animal food and intentional contamination). FDA tentatively concludes that it is appropriate to provide a sufficient time period following publication of the final regulation for facilities to come into compliance. The final regulation will contain provisions that affect which facilities are subject to section 418 and which provisions apply to particular facilities. Without these provisions of the regulation in effect, facilities would be uncertain as to the applicability of certain requirements to them. Further, FDA tentatively concludes that compliance with section 418 will be facilitated greatly by the detail and explanation that will be provided by the final regulation.

The current practices of many businesses are sufficient to satisfy some of the proposed requirements. However, the majority of businesses will need to make at least some changes if the proposed regulations are adopted. FDA recognizes that it can take time to implement a food safety system that would require, among other things, performance of a hazard analysis, development of preventive controls, and monitoring of preventive controls.

FDA is proposing that the final rule would be effective 60 days after publication in the **Federal Register**, with staggered compliance dates. However, we recognize that businesses of all sizes may need more time to comply with the new requirements established under FSMA. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA. FDA intends to work closely with the food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of this rule.

FDA also is proposing to modernize the existing CGMP requirements, and businesses already subject to current part 110 will be subject to the modernized CGMPs that would be established in proposed part 117. FDA believes that it is reasonable to allow for the same compliance periods for the modernized CGMPs as for the other provisions in proposed part 117 so that a facility would be subject to all of the relevant provisions in proposed part 117 at the same time. To provide for this staggered implementation of the modernized CGMPs, FDA is proposing to establish the revised regulations in a new part (i.e., part 117) so that current part 110 can remain unchanged and in effect for compliance purposes until all businesses have reached the date when they must be in compliance with new part 117. Thus, as discussed in section XVII of this document, we are proposing that current part 110 be removed on the date that is 3 years after the date of publication of the final rule.

VIII. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

A. Section 103(c) of FSMA

1. Clarification of the Activities That Are Included as Part of the Definition of the Term ''Facility'' Under Section 415 of the FD&C Act

Section 103(c)(1)(A) of FSMA requires the Secretary to ''publish a notice of proposed rulemaking in the **Federal Register** to promulgate regulations with respect to—(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d), as amended by [FSMA]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415.'' Section 103(c)(1)(B) of FSMA stipulates that such rulemaking ''shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term 'facility' under such section.'' Section 415 of the FD&C Act, in turn, directs the Secretary to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities) (the section 415 registration regulations).

To implement sections 103(c)(1)(A) and (B) of FSMA, in this document we are proposing to clarify the treatment of activities that are included as part of the definition of the term ''facility'' in section 415 of the FD&C Act in order to enhance the implementation of section 415. By doing so, we also clarify the coverage of section 418 of the FD&C Act, because section 418 applies to domestic and foreign facilities that are required to register under section 415 (see section 418(o)(2)) except where exemptions from section 418 apply. In the remainder of this section VIII of this document:

- We discuss the current legal and regulatory framework for farms under sections 415 and 418 of the FD&C Act, including requirements for registration of food facilities in the section 415 registration regulations. (See section VIII.B.)
- We explain why we tentatively conclude that rulemaking is needed to implement sections 103(c)(1)(A) and (B) of FSMA. (See section VIII.C.)
- We explain how the status of a food as a raw agricultural commodity (RAC) or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act. We also articulate a comprehensive set of organizing principles that form the basis for proposed revisions to the section 415 registration regulations. (See section VIII.D.)
- We describe our proposed revisions to the definitions in the section 415 registration regulations, based on the organizing principles articulated in section VIII.D, to clarify the treatment of activities that are included as part of the definition of the term ''facility'' in those regulations and to enhance and clarify the application of those definitions. We also describe conforming changes to part 1, subpart I (Prior Notice of Imported Food) (hereinafter the prior notice regulations, established under section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) (hereinafter the ''BT Act'')) and part 1, subpart J (Establishment, Maintenance, and Availability of Records) (hereinafter the section 414 recordkeeping regulations, established under section 414 of the FD&C Act). (See section VIII.E.)
- We describe the impact of the proposed revisions to the definitions in the section 415 registration regulations on farms and on ''farm mixed-type'' facilities. A ''farm mixed-type'' facility conducts activities that are outside the scope of the definition of ''farm'' (e.g., slicing or chopping fruits or vegetables) even though it also conducts activities that are within the scope of the definition of farm (e.g., growing and harvesting crops or raising animals). Conducting activities outside the definition of ''farm'' triggers the requirements in the section 415

registration regulations and, thus, brings the facility within the scope of section 418 of the FD&C Act. (See section VIII.F.)

2. Science-Based Risk Analysis Covering Specific Types of On-Farm Manufacturing, Processing, Packing and Holding Activities

Section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.'' In section VIII.G of this document, we describe a draft Qualitative Risk Assessment (the section 103(c)(1)(C) draft RA) (Ref. 115) we performed to satisfy this requirement.

3. Exemptions and Modified Requirements for Certain Facilities

Section 103(c)(1)(D)(i) of FSMA requires that, as part of the section 103(c) rulemaking, ''the Secretary shall consider the results of the science-based risk analysis * * * and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by [section 103 of FSMA]) including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201 [of FSMA]), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' Section 103(c)(1)(D)(ii) of FSMA provides that the exemptions or modifications described in section 103(c)(1)(D)(i) ''shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by [FSMA], if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act[.]'' In section VIII.H of this document, we discuss the results of the section 103(c)(1)(C) draft RA. In section VIII.I of this document, we set forth our tentative conclusions regarding combinations of on-farm manufacturing, processing, packing, and holding activities and foods determined to be low risk, considering the results of the section 103(c)(1)(C) draft RA. In section VIII.J of this document, we discuss a proposed approach to using the results of the section 103(c)(1)(C) draft RA for the purposes of section 421 of the FD&C Act. In section X.C.6 of this document, we discuss our proposal to exempt low-risk combinations of activities and foods from the requirements of section 418 of the FD&C Act when performed by farm mixed-type facilities that are small or very small businesses as would be defined in proposed § 117.3 (see discussion of the proposed definitions of ''small business'' and ''very small business'' in section X.B.4 of this document).

B. The Current Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

As noted in the previous section, section 415 of the FD&C Act directs the Secretary to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. Section 1.227 in the section 415 registration regulations includes definitions that are relevant to the scope of those regulations, including definitions for types of establishments (''facility'' and ''farm'') and for types of activities (''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing''). In relevant part, these definitions play a role in determining whether an establishment is a facility that must register with FDA and implement a provision (in section 415(b)(1) of the FD&C Act) exempting ''farms'' from the registration requirement in section 415. We have issued guidance to assist food facilities in complying with the section 415 registration regulations (hereinafter ''Food Facility Registration Guidance'') (Ref. 116).

Section 418(n) of the FD&C Act directs the Secretary to establish regulations implementing the requirements of section 418 for hazard analysis and risk-based preventive controls applicable to the owner, operator, or agent in charge of a ''facility.'' Section 418(o)(2) of the FD&C Act defines ''facility'' for the purpose of section 418 as ''a domestic or foreign facility that is required to register under section 415.''

Under the framework established by section 415 of the FD&C Act and the section 415 registration regulations, farms are establishments that do conduct activities described in the farm definition in § 1.227(b)(3) but do not conduct other activities (such as manufacturing/processing on food that is not consumed on that farm or another farm under the same ownership) that would trigger the requirements in the section 415 registration regulations. Because establishments that satisfy the definition of ''farm'' in § 1.227(b)(3) are not required to register under section 415, they do not satisfy the definition of ''facility'' in section 418(o)(2) of the FD&C Act and, thus, they are not subject to section 418 of the FD&C Act.

The current legal and regulatory framework provided in sections 415 and 418 of the FD&C Act, the section 415 registration regulations, and the Food Facility Registration Guidance is relevant to the FSMA section 103(c) rulemaking and the FD&C Act section 418(n) rulemaking that are the subjects of this document. That framework determines which establishments and activities are subject to the requirements of section 418 of the FD&C Act. We describe key provisions applicable to the current legal and regulatory framework in Table 1.

TABLE 1—KEY PROVISIONS APPLICABLE TO THE CURRENT LEGAL AND REGULATORY FRAMEWORK UNDER SECTIONS 415 AND 418 OF THE FD&C ACT

Provision of the Section 415 Registration Regulations or the FD&C Act	Definition or Requirement
§ 1.227(b)(2): Current definition of ''facility''	For the purposes of section 415 of the FD&C Act, a facility is, in relevant part, any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.

TABLE 1—KEY PROVISIONS APPLICABLE TO THE CURRENT LEGAL AND REGULATORY FRAMEWORK UNDER SECTIONS 415 AND 418 OF THE FD&C ACT—Continued

Provision of the Section 415 Registration Regulations or the FD&C Act	Definition or Requirement
§ 1.225: Requirement to register	The owner, operator, or agent in charge of either a domestic or foreign facility must register in accordance with the section 415 registration regulations if the facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless the facility qualifies for one of the exemptions in § 1.226.
§ 1.226(b): Exemption from registration for farms.	Farms are not subject to the registration requirement in § 1.225.
§ 1.227(b)(3): Current definition of ''farm''	Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term ''farm'' includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
§ 1.227(b)(5): Current definition of ''holding''.	Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
§ 1.227(b)(6): Current definition of ''manufacturing/processing''.	Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.
§ 1.227(b)(8): Current definition of ''packaging''.	Packaging (when used as a verb) means placing food into a container that directly contacts food and that the consumer receives.
§ 1.227(b)(9): Current definition of ''packing''.	Packing means placing food into a container other than packaging the food.
Section 418(o)(2) of the FD&C Act	A facility that is subject to the requirements of section 418 of the FD&C Act is a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act.

Together, the provisions described in Table 1 establish that a business qualifies as a ''farm'' that is exempt from the section 415 registration regulations if it satisfies the definition of ''farm'' in § 1.227(b)(3), including the activities performed, where the activities take place, where the food used in the activities comes from, and where the food is consumed:

- A farm is devoted to the growing and harvesting of crops. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.
- A farm can pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- A farm can manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

We note that FDA established the same definitions of the terms ''facility,'' ''farm,'' ''holding,'' ''manufacturing/processing,'' ''packaging,'' and ''packing'' in the section 414 recordkeeping regulations (§ 1.328), because farms are excluded from FDA's authority to establish recordkeeping requirements under section 414(b) of the FD&C Act.

C. Why This Rulemaking Is Needed

Farms are subject to many provisions of the FD&C Act and FDA's authorities thereunder, such as FDA's inspection authority under section 704 and the general adulteration provisions for food in section 402. FDA has long recognized that regulation of farms should be sensitive to the agricultural setting. As early as 1969, FDA exempted establishments ''engaged solely in the harvesting, storage, or distribution'' of raw agricultural commodities from certain regulatory requirements (34 FR 6977 at 6980, April 26, 1969). The BT Act provided FDA with the authority to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA, and to issue regulations regarding the establishment and maintenance of certain records (codified as sections 415 and 414 of the FD&C Act, respectively). Sections 415 and 414 explicitly exclude ''farms,'' but do not define that term. In notice and comment rulemaking implementing these provisions, FDA developed a definition of the term ''farm.'' FDA first proposed to define ''farm'' as a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. Under that proposed definition, the term ''farm'' would also have included (i) facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and (ii) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership (68 FR 5378 at 5418, February 3, 2003).

FDA received comments stating that the proposed definition was too narrow because it would not include farms that engage in activities traditionally performed on farms for nearly all commodities, such as washing, trimming outer leaves, and cooling (68 FR 58894 at 58905, October 10, 2003). Accordingly, to reflect the intent of Congress to exempt establishments engaging in activities farms traditionally perform from the section 415 registration regulations, in the final rule FDA revised the first part of the farm definition in § 1.227(b)(3) to state that a farm is a facility in one general location that is devoted to the growing *and harvesting* of crops, the raising of animals (including seafood), or both, *and that washing, trimming outer leaves, and cooling of food are considered part of harvesting* (68 FR 58894 at 58905) (emphasis added). FDA also established the same definition of ''farm'' at § 1.328 for the purpose of exempting farms from the section 414 recordkeeping regulations (69 FR 71652, December 9, 2004). In post-rulemaking

guidances implementing the section 415 registration regulations and the section 414 regulations, FDA further addressed and interpreted the farm definition with the goal of doing so in a manner recognizing the traditional activities of establishments commonly recognized to be farms (see the Food Facility Registration Guidance (Ref. 116) and ''Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4), September 2006 (hereinafter ''Recordkeeping Guidance'' (Ref. 117)).

Farm Mixed-Type Facilities

Consistent with the current legal and regulatory framework under sections 415 and 418 of the FD&C Act and the section 415 registration regulations, activities within the farm definition in § 1.227(b)(3) would not be subject to the requirements of this proposed rule. Activities that are not within the farm definition and that trigger the section 415 registration regulations would be subject to the requirements of section 418 of the FD&C Act (and therefore to the relevant parts of this proposed rule), except where an exemption applies. (For a discussion of proposed exemptions, see section X.C of this document.)

For the purposes of this document, a ''farm mixed-type facility'' is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but that also conducts activities that trigger the section 415 registration regulations (see the discussion of our proposed definition of ''farm mixed-type facility'' in section VIII.E of this document). Section 418 of the FD&C Act does not explicitly address whether a farm mixed-type facility is subject to section 418 with respect to all of its activities or only with respect to its activities that trigger the section 415 registration regulations. Considering the text of section 103 of FSMA and the FD&C Act as a whole, FDA tentatively concludes that a farm mixed-type facility should be subject to section 418 only with respect to its activities that trigger the section 415 registration regulations, and not with respect to its activities that are within the farm definition. Put another way, we would apply section 418 only to the ''non-farm'' portion of the establishment's activities, and not to the ''farm'' portion of its activities.

Because section 418(o)(2) of the FD&C Act defines the term ''facility'' for the purposes of section 418 to mean only those facilities required to register under section 415 of the FD&C Act, FDA tentatively concludes that Congress intended the exemptions from the section 415 registration regulations, including the farm exemption in § 1.226(b), to be meaningful for the purposes of defining the applicability of section 418. Section 418(a) requires the owner, operator, or agent in charge of a facility that is required to register under section 415 to ''evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility'' and to take other steps discussed more fully in section XII of this document, including identifying and implementing preventive controls, monitoring preventive controls, and maintaining records. The use of the phrase ''food manufactured, processed, packed, or held by the facility'' in section 418(a) parallels the language in section 415(a)(1) providing that ''[t]he Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary.'' Considering the text of FSMA and the FD&C Act as a whole, FDA tentatively concludes that only those manufacturing, processing, packing, or holding activities that trigger registration under the section 415 registration regulations should be considered to be manufacturing, processing, packing, or holding of food by a facility for the purposes of section 418. Put another way, FDA tentatively concludes that a mixed-type facility should only be subject to section 418 with respect to its activities that actually trigger the section 415 registration regulations, and not with respect to its other activities, at the same location, that would not trigger the section 415 registration regulations. To conclude otherwise would mean that, for example, the farm exemption from registration would be rendered irrelevant to the coverage of section 418, except for activities on farms that will be subject to requirements under section 419 of the FD&C Act (see the discussion of the exemption provided by section 418(k) of the FD&C Act to such farms in section X.C.5 of this document). Under such an interpretation many ''farm'' portions of farm mixed-type facilities would be subject to section 418, including, for example, dairies, egg farms, farms raising livestock for food, and farms growing produce that is not subject to requirements under section 419. However, section 103(c)(1)(D) of FSMA, which directs FDA to consider exempting or modifying the requirements of section 418 for activities conducted by a farm mixed-type facility outside the farm exemption, seems to mean that Congress did not intend the ''farm'' portion of such a facility to be covered by section 418, even though Congress intended the ''non-farm'' portions of such a facility to be subject to section 418 (including under modified requirements) (provided that FDA concluded that it was appropriate to do so after conducting the science-based risk analysis required by section 103(c)(1)(C) of FSMA). (See section VIII.G for a discussion of the analysis FDA conducted and section VIII.H of this document for a discussion of FDA's proposed actions in light of that analysis).

Therefore, unless an exemption from section 418 of the FD&C Act applies, FDA tentatively concludes that a facility that is required to register under section 415 of the FD&C Act should be subject to section 418 with respect to all its activities that trigger the section 415 registration regulations, but not with respect to its activities that would not trigger the section 415 registration regulations (such as activities within the farm definition set forth in § 1.227(b)(3)). Thus, it is particularly important to clarify the classification of various activities included in the ''facility'' definition in section 415 as manufacturing, processing, packing, or holding—and in doing so to clarify the scope of the farm definition in § 1.227(b)(3)—to make clear the extent to which a farm mixed-type facility must comply with section 418.

Clarification of Activities Relevant to Farm Mixed-Type Facilities

At the time FDA developed the farm definition and its interpretations of that definition, the practical impact of an activity's classification as inside or outside that definition was limited to the potential to trigger the section 415 registration regulations and the section 414 recordkeeping regulations. With the advent of FSMA, the scope of the farm definition has taken on more importance because, for example and as discussed in this section, activities within the farm definition are not subject to section 418 of the FD&C Act, but activities outside the farm definition are subject to section 418. Therefore, it is important that FDA clarify the scope of the farm definition, including the classification of manufacturing, processing, packing and holding activities relevant to that definition, and adjust it if necessary and appropriate to enhance implementation of section 418 of the FD&C Act, as well as section 415 of the FD&C Act. Accordingly, in the remainder of this section VIII FDA articulates a comprehensive set of organizing principles that would form

the basis for our proposal for classifying activities to more accurately reflect the scope of activities traditionally conducted by farms and to allow for more certainty among industry with regard to how their activities will be regulated. We seek comment on this proposal.

D. Organizing Principles for How the Status of a Food as a Raw Agricultural Commodity or as a Processed Food Affects the Requirements Applicable to a Farm Under Sections 415 and 418 of the FD&C Act

1. Statutory Framework for Raw Agricultural Commodities and Processed Food

To clarify the scope of the farm definition, FDA considered how the activities of farms relate to the statutory concepts of ''raw agricultural commodity'' and ''processed food.'' The FD&C Act defines ''raw agricultural commodity'' and ''processed food'' in relation to each other, and identifies certain activities that transform a RAC into a processed food and others that do not. Section 201(r) of the FD&C Act (21 U.S.C. 321(r)) defines ''raw agricultural commodity'' to mean ''any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.'' Section 201(gg) of the FD&C Act (21 U.S.C. 321(gg)) defines ''processed food'' to mean ''any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.'' In addition, section 201(q)(1)(B)(i)(II) of the FD&C Act (which defines pesticide chemicals) contains the following language regarding activities that do not transform a RAC into a processed food: ''the treatment [with pesticide chemicals] is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).''

The status of a food as a RAC or processed food is relevant for many different purposes under the FD&C Act. For example, under section 403(q)(4) of the FD&C Act (21 U.S.C. 343(q)(4)), FDA has established a voluntary nutrition labeling program that applies to RACs but not to processed foods. Under 403(w) of the FD&C Act (21 U.S.C. 343(w)), labeling requirements related to major food allergens apply to processed foods but do not apply to RACs. Under sections 201(q), 403(k), 403(l), and 408 of the FD&C Act (21 U.S.C. 321(q), 343(k), 343(l), and 346a), the status of a food as a RAC has an impact on the manner in which pesticide chemicals and their residues are regulated. FSMA created more provisions in the FD&C Act and elsewhere that take status as a RAC or processed food into account, including section 417(f) of the FD&C Act (21 U.S.C. 350f(f)), establishing notification requirements for reportable foods that do not apply to fruits and vegetables that are RACs; section 418(m) of the FD&C Act, which authorizes FDA to exempt or modify the requirements for compliance under section 418 with respect to facilities that are solely engaged in the storage of RACs other than fruits and vegetables intended for further distribution or processing; section 419(a)(1)(A) of the FD&C Act (21 U.S.C. 350h(a)(1)(A)), which authorizes FDA to establish minimum science-based standards applicable to certain fruits and vegetables that are RACs; and section 204(d)(6)(D) of FSMA (21 U.S.C. 2223(d)(6)(D)), which contains special provisions for commingled RACs applicable to FDA's authority under section 204 of FSMA to establish additional recordkeeping requirements for high risk foods. FDA has also established by regulation an exemption from the current CGMP requirements applicable to establishments engaged solely in the harvesting, storage, or distribution of one or more RACs (§ 110.19). (We discuss this exemption in detail in section X.C.9 of this document.)

The term ''raw agricultural commodity'' and similar terms also appear in other Federal statutes. While these statutes are not implemented or enforced by FDA and do not directly impact the interpretation of the definitions in sections 201(r) and 201(gg) of the FD&C Act, they do provide some suggestions about what ''raw agricultural commodity'' and related concepts can mean in various circumstances. For example, the Secretary of Transportation may prescribe commercial motor vehicle safety standards under 49 U.S.C. 31136, but the Motor Carrier Safety Improvement Act of 1999 (Pub. L. 106–159, title II, Sec. 229, Dec. 9, 1999), as added and amended by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109–59, title IV, Sec. 4115, 4130, Aug. 10, 2005), provided an exemption from maximum driving or on-duty times for drivers transporting ''agricultural commodities'' or farm supplies within specific areas during planting and harvest periods. In that circumstance, ''agricultural commodity'' is defined as ''any agricultural commodity, non-processed food, feed, fiber, or livestock * * * and insects'' (49 U.S.C. 31136 note). Another example is 19 U.S.C. 1677(4)(E), which provides for certain circumstances in which producers or growers of raw agricultural products may be considered part of the industry producing processed foods made from the raw agricultural product for the purposes of customs duties and tariffs related to such processed foods. In that circumstance, ''raw agricultural product'' is defined as ''any farm or fishery product'' (19 U.S.C. 1677(4)(E)). These statutes are informative in that they suggest that the ''raw agricultural commodity'' concept describes and signifies the products of farms in their natural states, or, in other words, that which a farm exists to produce on a basic level.

2. Interpretive Documents and Guidance Regarding Whether an Activity Transforms a Raw Agricultural Commodity Into a Processed Food

Because the status of a food as a RAC or processed food is of great importance in defining the jurisdiction of FDA and EPA over antimicrobial substances, FDA and EPA have developed guidance regarding whether or not various activities transform RACs into processed foods. FDA and EPA jointly issued a legal and policy interpretation of the agencies' jurisdiction under the FD&C Act over antimicrobial substances used in or on food (hereinafter the ''1998 Joint EPA/FDA Policy Interpretation'') (63 FR 54532, October 9, 1998). In 1999, FDA issued guidance addressing several of the issues discussed in the 1998 Joint EPA/FDA Policy Interpretation. (See Guidance for Industry: Antimicrobial Food Additives, July 1999 (hereinafter ''Antimicrobial Guidance'') (Ref. 118)). As discussed in these documents, FDA and EPA agreed that the following ''post-harvest'' activities do not transform a RAC into processed food within the meaning of that term in section 201(gg) of the FD&C Act: ''washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems, and husks'' (Ref. 118, section 7 and 63 FR 54532 at 54541). FDA and EPA also agreed that the following activities do transform a RAC into a processed food: ''canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling'' (Ref. 118, section 7 and 63 FR 54532 at 54541). In addition, these documents set forth the conclusion of

EPA and FDA that drying a RAC causes it to become a processed food, unless the drying is for the purpose of facilitating storage or transportation of the commodity (Ref. 118, section 7 and 63 FR 54532 at 54541–2); this conclusion was based on EPA's policy statement on the status of dried commodities as RACs (61 FR 2386, January 25, 1996). FDA and EPA also identified slaughter of animals for food and activities done to carcasses post-slaughter as ''processing'' for the purposes of the processed food definition (Ref. 118, section 7 and 63 FR 54532 at 54542). Table 2 summarizes activities that cause food RACs to become processed foods and activities that do not change the status of a food RAC, as provided in the FD&C Act and addressed in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance.

TABLE 2—THE EFFECT OF ACTIVITIES ON RACS THAT ARE FOODS

Activities that change a RAC into a processed food	Activities that do not change the status of a RAC.
Canning.	Application of pesticides (including by washing, waxing, fumigation, or packing).
Chopping.	Coloring.
Cooking.	Drying for the purpose of storage or transportation.
Cutting.	Hydro-cooling.
Drying that creates a distinct commodity.	Otherwise treating fruits in their unpeeled natural form.
Freezing.	Packing.
Grinding.	Refrigeration.
Homogenization.	Removal of leaves, stems, and husks.
Irradiation.	Shelling of nuts.
Milling.	Washing.
Pasteurization.	Waxing.
Peeling.	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant.
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering.	
Slicing.	
Activities that alter the general state of the commodity.	

The summary in Table 2 demonstrates that the activities that transform a RAC into a processed food (and are sometimes therefore referred to as ''processing'' in the context of a food's status as a RAC or processed food) are not coextensive with the definition of ''manufacturing/processing'' that FDA established in §§ 1.227(b)(6) and 1.328 for the purposes of the section 415 registration regulations and the section 414 recordkeeping regulations, respectively. The definition of ''Manufacturing/processing'' in those regulations includes most food-handling activities because it is satisfied by any degree of ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' In contrast, transforming a RAC into a processed food seems to require meeting a threshold of altering the general state of the commodity (Ref. 118, section 7 and 63 FR 54532 at 54541), sometimes referred to as transformation of the RAC into a new or distinct commodity (61 FR 2386 at 2388). Because the activities that transform a RAC into a processed food are not coextensive with the definition of ''manufacturing/processing'' in §§ 1.227(b)(6) and 1.328, a given activity may be manufacturing/processing under the current definition in §§ 1.227(b)(6) and 1.328 without transforming a RAC into a processed food. Examples of such activities include coloring, washing, and waxing.

3. The Organizing Principles

The current section 415 registration regulations, section 414 recordkeeping regulations, and related guidances demonstrate that some activities may be classified differently on farms and off farms. For example, ''washing'' is an example of manufacturing/processing under the definition of that term in §§ 1.227(b)(6) and 1.328. However, ''washing'' produce is identified as part of harvesting under the farm definition in §§ 1.227(b)(3) and 1.328, so washing on farms is harvesting rather than manufacturing/processing. To date, FDA has not articulated organizing principles explaining these differences. In this document, we are tentatively articulating the following organizing principles to explain and clarify the basis for our proposed revisions to the definitions that classify activities on-farm and off-farm in the section 415 registration regulations and in the section 414 recordkeeping regulations, and that we interpret in guidances. In section VIII.E of this document, we propose to incorporate these organizing principles into the definitions, previously established in §§ 1.227 and 1.328, that classify activities related to foods on farms and farm mixed-type facilities. FDA tentatively concludes that doing so would more accurately reflect which activities of these establishments should fall within the farm definition.

a. First organizing principle. The statutes we describe in section VIII.D.1 of this document, and previous interpretations of the concepts of RACs and processed food as set forth in the 1998 Joint EPA/FDA Policy Interpretation and the Antimicrobial Guidance, lead FDA to tentatively conclude that the basic purpose of farms is to produce RACS and that RACs are the essential products of farms. This tentative conclusion is the first organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

b. Second organizing principle. In light of the first organizing principle (i.e., that the basic purpose of farms is to produce RACs, and that RACs are the essential products of farms), we also tentatively conclude that activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm'' in §§ 1.227(b)(3) and 1.328. Doing so would appropriately implement the intent of Congress (under sections 415(b)(1) and 414(b) of the FD&C Act) that FDA

exempt ''farms'' from the section 415 registration regulations and the section 414 recordkeeping regulations. This is the case even if the same activities off-farm would be considered to be manufacturing/processing under the definition of that term in §§ 1.227(b)(6) and 1.328, because those activities involve ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food.'' This tentative conclusion regarding a special classification for on-farm activities is the second organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

c. Third organizing principle. In light of the first organizing principle (i.e., that the basic purpose of farms is to produce RACs, and that RACs—but not processed foods—are the essential products of farms) FDA tentatively concludes that the second organizing principle (i.e., the special classification of on-farm activities) should only apply to RACs. Thus, the third organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities is that activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food. A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm, thereby opting to become a farm mixed-type facility subject to the section 415 registration regulations, section 414 recordkeeping regulations, and other requirements linked to the registration requirement of section 415 of the FD&C Act by FSMA (such as compliance with section 418 of the FD&C Act).

d. Fourth organizing principle. In light of the first organizing principle (i.e., that the essential purpose of a farm is to produce RACs, and that RACs are the essential products of farms), FDA also tentatively concludes that the second organizing principle (i.e., the special classification of on-farm activities) should only apply to RACs grown or raised on the farm itself or on other farms under the same ownership because the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce. (For the purposes of this discussion, FDA refers to RACs grown or raised on a farm or another farm under the same ownership as a farm's ''own RACs,'' in contrast to RACs grown on a farm under different ownership, which FDA refers to as ''others' RACs.'') Notably, when FDA first undertook to define ''farm,'' it received a comment implicitly recognizing this, urging the agency to define farms to include typical post-harvesting operations, *if all food is grown on the farm* (emphasis added) (68 FR 5378 at 5379). Therefore, activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce. In general, when a farm opts to perform activities outside the farm definition (and, thus, becomes a farm mixed-type facility), the establishment's activities that are within the farm definition should be classified as manufacturing/processing, packing, or holding in the same manner as for a farm that is not a mixed-type facility, but the activities that are outside the farm definition should be classified in the same manner as for an off-farm food establishment. This is the fourth organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

e. Fifth organizing principle. FDA tentatively concludes that manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition because otherwise farms could not feed people and animals on the farm without being required to register under section 415 of the FD&C Act. This is the fifth organizing principle that we would incorporate into the definitions that classify activities related to foods on farms and farm mixed-type facilities.

f. Summary of organizing principles. For the convenience of the reader, Table 3 summarizes the organizing principles that FDA is articulating in this document to explain and clarify the basis for our proposed revisions to the definitions that classify activities on-farm and off-farm in the section 415 registration regulations and in the section 414 recordkeeping regulations, and that we interpret in guidances.

TABLE 3—SUMMARY OF ORGANIZING PRINCIPLES REGARDING CLASSIFICATION OF ACTIVITIES ON-FARM AND OFF-FARM

No.	Organizing Principle
1	The basic purpose of farms is to produce RACs and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm'' in §§ 1.227 and 1.328.
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
5	Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

E. Proposed Revisions to 21 CFR Part 1

1. Proposed Redesignation of the Definitions in § 1.227

FDA is proposing to redesignate all definitions in the section 415 registration regulations (i.e., current § 1.227) to eliminate paragraph designations (such as (a), (b), (1), (2), and (3)). Paragraph designations are not necessary when definitions are presented in alphabetical order. New definitions that FDA is proposing to add to the section 415 registration regulations and the section 414 recordkeeping regulations would be added in alphabetical order.

2. Proposed Substantive Revisions to the Definitions in §§ 1.227 and 1.328

FDA is proposing to revise the definitions in the section 415 registration regulations (§ 1.227) and in the section 414 recordkeeping regulations (§ 1.328), and to add new definitions to those regulations, to reflect the organizing principles articulated in section VIII.D of this document and to clarify how those

definitions apply to specific activities depending on where the activities take place, the food used in the activities, where the food comes from, and where the food is consumed.

FDA is proposing to add a new definition of the term ''Mixed-type facility'' to §§ 1.227 and 1.328. ''Mixed-type facility'' would mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. This term and its definition were initially developed in the preamble to the proposed rule on food facility registration (68 FR 5378 at 5381) and in the interim final rule on food facility registration (68 FR 58894 at 58906–7, 58914, 58934–8) and would be codified in our proposed revisions to §§ 1.227 and 1.328 with the same meaning. The proposed definition would also provide, as an example of such a facility, a definition of a ''farm mixed-type facility.'' A ''farm mixed-type facility'' would be defined as an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. FDA tentatively concludes that it is necessary to define this term to satisfy the directives of FSMA section 103(c) to enhance the implementation of section 415 of the FD&C Act, clarify the activities that are included as part of the term facility under section 415, and to conduct this rulemaking addressing activities that constitute on-farm packing or holding of food not grown, raised, or consumed on such farm or another farm under the same ownership and activities that constitute on-farm manufacturing or processing of food not consumed on that farm or another farm under common ownership. Because the specific classes of activities mentioned in FSMA section 103(c) are, by definition, on-farm activities that do not fall within the farm definition, Congress has explicitly directed FDA to engage in rulemaking addressing establishments that conduct activities that are outside the farm definition on farms. Accordingly, FDA is proposing to define the term ''farm mixed-type facility'' to refer to these establishments.

FDA is proposing to add a new definition of the term ''Harvesting'' to §§ 1.227 and 1.328. Harvesting would apply to farms and farm mixed-type facilities and be defined as activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting would be limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting would not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership would be listed as examples of harvesting. This proposed definition would include the same examples of ''harvesting'' that were previously part of the farm definition (washing, trimming of outer leaves, and cooling) and would add other examples to help clarify the scope of the definition of harvesting. FDA also proposes to make clear that these activities are ''harvesting'' when conducted on any of a farm's own RACs, not just ''produce.'' For example, unpasteurized shell eggs are RACs, and washing such eggs on the farm on which the eggs were produced would be part of harvesting the eggs. ''Harvesting'' is a category of activities that is only applicable to farms and farm mixed-type facilities. Activities that would be ''harvesting'' when performed on a farm on the farm's own RACs would be classified differently under other circumstances, such as at a processing facility that is not on a farm, or when performed by a farm on others' RACs. For example, at an off-farm processing facility that pasteurizes eggs, washing the unpasteurized shell eggs after they are received would not be ''harvesting'' because it is not being performed on the farm that produced the eggs (or another farm under the same ownership). Instead, washing eggs at the off-farm processing facility would be ''manufacturing/processing,'' because it involves preparing, treating, modifying or manipulating food.

FDA is proposing to revise the definition of ''Holding'' in current §§ 1.227(b)(5) and 1.328 by adding to the existing definition an expanded definition applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just storage of food would be classified as ''holding'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, fumigating or otherwise treating a farm's own RACs against pests for the purpose of safe and effective storage would be ''holding'' under this proposed definition. However, fumigating or otherwise treating food against pests under other circumstances (such as off-farm or by a farm handling others' RACs) would not be ''holding'' food because it is not storage of food, which would remain the definition of holding applicable to most circumstances.

FDA is proposing to revise the definition of ''Manufacturing/processing'' in current §§ 1.227(b)(6) and 1.328 by adding to the existing definition a criterion applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. Under this proposed revision, expanded definitions of ''packing'' and ''holding,'' and the extra category ''harvesting'' would apply to activities performed by farms and farm mixed-type facilities on their own RACs. These expanded and extra categories would not apply off-farm or to foods other than a farm's own RACs or a farm mixed-type facility's own RACs. Thus, some activities that would otherwise be manufacturing/processing would instead be defined as packing, holding, or harvesting by virtue of being performed by a farm or farm mixed-type facility on its own RACs. Accordingly, these activities would not be manufacturing/processing because they would already be classified into the expanded definitions of packing or holding, or into the extra category of harvesting.

FDA is proposing to revise the definition of ''Packing'' in current §§ 1.227(b)(9) and 1.328 by adding to the existing definition an expanded definition applicable to farms and farm mixed-type facilities. The proposed revision would state that, for farms and farm mixed-type facilities, packing would also include activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C

Act, into a processed food as defined in section 201(gg) of the FD&C Act. This would mean that more activities than just placing food into a container other than packaging would be classified as ''packing'' when a farm or farm mixed-type facility performs those activities on its own RACs. For example, packaging (placing food into a container that directly contacts the food and that the consumer receives) a farm's own RACs would be ''packing'' under this definition because farms traditionally do this to provide greater protection for fragile RACs than would be possible if the RACs were placed in containers other than the consumer container, and because this activity does not transform a RAC into a processed food. However, packaging food under other circumstances would not be ''packing'' food because packaging is explicitly excluded from the definition of packing applicable to most circumstances (placing food into a container other than packaging). Other examples of activities that could be packing when performed by a farm or a farm mixed-type facility on its own RACs include packaging or packing a mix of RACs together (e.g., in a bag containing three different colored bell peppers, or a box of mixed produce for a community sponsored agriculture program farm share); coating RACs with wax, oil, or resin coatings used for the purposes of storage or transport; placing stickers on RACs; labeling packages containing RACs; sorting, grading, or culling RACs; and drying RACs for the purpose of storage or transport.

Table 4 provides examples of how we would classify activities conducted off-farm and on-farm (including farm mixed-type facilities) using these proposed revisions to the definitions in the section 415 registration regulations and in the section 414 recordkeeping regulations.

TABLE 4—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM

[Including farm mixed-type facilities]

Classification	Off-Farm	On-Farm (Including farm mixed-type facilities)
Harvesting	*Notes:* Not applicable. Harvesting is a classification that only applies on farms and farm mixed-type facilities.	*Notes:* Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting is limited to activities performed on RACs on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that change a RAC into processed food. Activities that are harvesting are within the farm definition.
Harvesting	*Examples:* Not applicable	*Examples:* Activities that fit this definition when performed on a farm's ''own RACs'' (a term we use to include RACs grown or raised on that farm or another farm under the same ownership) include gathering, washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling. These activities, performed on a farm's own RACs, are inside the farm definition.
Packing	*Notes:* Placing food in a container other than packaging the food (where packaging means placing food into a container that directly contacts the food and that the consumer receives).	*Notes:* Placing food in a container other than packaging the food (using the same definition of packaging), or activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on that farm or another farm under the same ownership for storage or transport. Packing does not include activities that change a RAC into a processed food. Activities that are packing are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
Packing	*Examples:* Putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates).	*Examples:* Activities that fit the definition of packing when performed on a farm's own RACs include packaging, mixing, coating with wax/oil/resin for the purpose of storage or transport, stickering/labeling, drying for the purpose of storage or transport, and sorting/grading/culling. These activities, performed on a farm's own RACs, are inside the farm definition.
		Activities that fit the definition of packing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, include putting individual unit cartons into a larger box used for shipping, and putting articles of produce in non-consumer containers (such as shipping crates)—the same activities that fit the definition of packing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.
Holding	*Notes:* Storage of food	*Notes:* Storage of food, or activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on that farm or another farm under the same ownership. Holding does not include activities that change a RAC into a processed food. Activities that are holding are within the farm definition when they are performed on food grown, raised, or consumed on that farm or another farm under the same ownership; under any other circumstances they are outside the farm definition.
Holding	*Example:* Storing food, such as in a warehouse.	*Examples:* activities that fit the definition of holding when performed on a farm's own RACs include fumigating during storage, and storing food, such as in a warehouse. These activities, performed on a farm's own RACs, are inside the farm definition.
		An activity that fits the definition of holding when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership, is storing food, such as in a warehouse—the same activity that fits the definition of holding off farm. This activity, performed on food other than a farm's own RACs, is outside the farm definition unless done on food for consumption on the farm.

TABLE 4—CLASSIFICATION OF ACTIVITIES CONDUCTED OFF-FARM AND ON-FARM—Continued

[Including farm mixed-type facilities]

Classification	Off-Farm	On-Farm (Including farm mixed-type facilities)
Manufacturing/ Processing	*Notes:* Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food. Includes packaging (putting food in a container that directly contacts food and that the consumer receives).	*Notes:* Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food; except for things that fall into the categories of harvesting, packing, or holding (see rows above). Activities that are manufacturing/processing are outside the farm definition unless done on food for consumption on the farm.
Manufacturing/ Processing	*Examples:* Activities that fit this definition include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing.	*Examples:* Activities that fit the definition of manufacturing/processing when performed on a farm's own RACs include slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, coating with things other than wax/oil/resin, drying that creates a distinct commodity, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing. These activities, performed on a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.
	.....	Activities that fit the definition of manufacturing/processing when performed on a farm on any other foods, including RACs grown or raised on a farm not under the same ownership include washing, trimming of outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, cooling, packaging, mixing, coating, stickering/labeling, drying, sorting/grading/culling not incidental to packing or holding, fumigating, slaughtering animals or post-slaughter operations, irradiation, cutting/coring/chopping/slicing, canning, artificial ripening, cooking, pasteurizing/homogenizing, infusing, distilling, salting, smoking, grinding/milling, and freezing—the same activities that fit the definition of manufacturing/processing off farm. These activities, performed on food other than a farm's own RACs, are outside the farm definition unless done on food for consumption on the farm.

3. Proposed Technical Amendments and Conforming Changes

As a technical amendment for clarity and for consistency with our current approach to citing the FD&C Act in new regulations, FDA is proposing to delete the definition of ''Act'' in current § 1.227 of the section 415 registration regulations and revise all remaining definitions in current § 1.227 to refer to ''the Federal Food, Drug, and Cosmetic Act'' rather than ''the act.'' As a conforming change, FDA is proposing to revise current § 1.241 in the section 415 registration regulations to refer to ''the Federal Food, Drug, and Cosmetic Act'' rather than ''the act.''

Likewise, as a technical amendment for clarity and for consistency with our current approach to citing the FD&C Act in new regulations, FDA is proposing to delete the definition of ''Act'' in current § 1.328 of the section 414 recordkeeping regulations and revise all remaining definitions in current § 1.328 to refer to ''the Federal Food, Drug, and Cosmetic Act'' rather than ''the act.'' As a conforming change, FDA is proposing to revise current §§ 1.361 and 1.363 in the section 414 registration regulations to refer to ''the Federal Food, Drug, and Cosmetic Act'' rather than ''the act.''

As a conforming change to the proposed definition of ''harvesting,'' FDA is proposing to revise the definition of ''Farm'' in current §§ 1.227(b)(3) and 1.328 to delete examples of harvesting that currently appear in that definition. With the proposed new, separate definition of harvesting, it would be redundant to retain the examples of harvesting within the definition of ''Farm.''

As a conforming change to the proposed redesignation of § 1.227 to eliminate paragraph designations, FDA is proposing to revise § 1.276(b)(9) in the prior notice regulations to cross-reference § 1.227 (without any paragraph designations) rather than to cross-reference § 1.227(b)(6).

F. Impact of Proposed Revisions to the Definitions in 21 CFR Part 1

1. Approach

FDA has previously addressed whether various activities fall within the farm definition or not and, as discussed more fully in sections VIII.F.2 through VIII.F.5 of this document, has provided guidance on these issues in the rulemakings establishing the section 415 registration regulations and the section 414 recordkeeping regulations and in accompanying guidance (Ref. 116) (Ref. 117). For most of the activities FDA has previously addressed, applying the proposed definitions described in section VIII.E of this document would result in the same classification with respect to whether the activities are within the farm definition or not. However, because we have not previously articulated a comprehensive set of organizing principles that form the basis for classification of activities, in some cases the classification of an activity (e.g., packing, holding, or harvesting), or the rationale leading to the classification of an activity, may be different under the proposed revisions to the definitions in part 1 than under the current definitions in part 1.

In sections VIII.F.2 through VIII.F.5 of this document, we discuss several examples of activities that we previously addressed and interpreted during the rulemakings to establish the section 415 registration regulations and the section 414 recordkeeping

regulations, or in related guidances. We also explain what, if any, impact our proposed revisions to the definitions in part 1 would have on our interpretation of whether or how an activity conducted on a farm or a farm mixed-type facility would be within the farm definition or would be outside the farm definition (and, thus, trigger the section 415 registration regulations and be within the scope of section 418 of the FD&C Act). We focus on examples of activities where we consider that the proposed revisions to the definitions in part 1 would result in some change in outcome. For the convenience of the reader, in section VIII.F.6 of this document we provide a table summarizing these examples.

In sections VIII.F.2 through VIII.F.5 of this document, for the sake of simplicity, we discuss activities that would be classified as manufacturing/processing outside the farm definition under this proposal, without stating each time that such activities would still be within the farm definition if performed on food for a farm or farm mixed-type facility's own consumption. The discussion below should not be read to suggest that the activities discussed could not be within the farm definition if they were performed on food for a farm or farm mixed-type facility's own consumption.

2. Application of Pesticides to a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities

The general term ''treating'' is part of the definition of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, and would remain in the proposed revision to that definition. FDA previously addressed ''treating against pests'' on farms and farm mixed-type facilities in the preamble to the interim final rule on food facility registration (68 FR 58894 at 58905), the Food Facility Registration Guidance (Questions 2.5, 2.6, and 11.1) (Ref. 116), and the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562, 71587, December 9, 2004). In those documents, FDA previously concluded that treating crops against pests by applying pesticides prior to harvest is an integral part of growing crops and is therefore ''growing'' within the farm definition. For other post-harvest pesticide applications FDA previously concluded that the applications are manufacturing/processing outside the farm definition, because such applications are directed at the food rather than at the entire plant. However, for one specific postharvest pesticide application (i.e., applying wash water containing chlorine), FDA previously concluded both that some uses are washing within the farm definition and that another use is manufacturing/processing outside the farm definition. Specifically, FDA previously concluded that the following two uses of water containing chlorine are washing within the farm definition: (1) The application by a farm of chlorinated water from public or other water supplies that are chlorinated for other purposes and (2) the application by a farm of wash water containing chlorine added by the farm to wash water at levels below 200 parts per million (ppm) total chlorine. FDA also previously concluded that the application by a farm of wash water containing chlorine added by the farm to wash water at levels above 200 ppm is manufacturing/processing outside the farm definition because such levels constitute treating the crop against pests rather than washing.

Some but not all of these previous conclusions regarding the application of a pesticide to a farm or farm mixed-type facility's own RACs would change under the proposed revisions to part 1. Under both the current definitions in part 1 and the proposed revisions to those definitions, treatment of food crops against pests before harvest while the crop is still in the growing area has been, and would continue to be, considered an inherent part of the growing process and thus classified within the farm definition. Thus, the classification of such treatments would not be affected by the proposed revisions to part 1.

However, under the proposed revisions to part 1 FDA would now classify pesticide treatments of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of safe or effective storage to be holding within the farm definition rather than manufacturing/processing outside the farm definition. An example of such activity is fumigating a farm's own raw nuts to prevent insect infestation and damage during the potentially long storage period of the nuts. FDA is aware that such treatments are traditionally performed by farms and may be a practical necessity for the preservation of some crops during storage, and such treatments do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of ''holding'' applicable to farms and farm mixed-type facilities with respect to their own RACs.

Likewise, under the proposed revisions to part 1 FDA would now classify pesticide treatment of a farm's own RACs or a farm mixed-type facility's own RACs for the purpose of removing the crop from the growing area and preparing it for use as food to be harvesting. An example of such activity is washing a crop in water containing an antimicrobial chemical after removing the crop from the growing area. Generally, antimicrobial chemicals are intended only to ensure the safety of the wash water. However, if an antimicrobial chemical was also intended to reduce the microbial load on the crop itself as a safety measure, under the proposed revisions to part 1 addition of that antimicrobial chemical to reduce the microbial load on a farm's own RACs or a farm mixed-type facility's own RACs would now be classified within the farm definition rather than be classified as manufacturing/processing outside the farm definition. For example, the application of wash water containing chlorine added by the farm at levels above 200 ppm to its own RACs would now be classified as washing and/or treating (depending on the circumstances), either of which would be harvesting within the farm definition rather than as manufacturing/processing outside the farm definition. FDA is aware that such treatments are traditionally performed by farms and that they are part of preparing the crop for safe use as food, and such treatments do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of ''harvesting'' applicable to farms and farm mixed-type facilities with respect to their own RACs. Except for the two examples discussed above where FDA previously concluded that certain applications of water containing chlorine are washing within the farm definition, the classification of washing a crop in water containing an antimicrobial chemical as within the farm definition would represent a change from its previous classification as manufacturing/processing outside the farm definition.

Continuing to use the general term ''treating'' in the proposed definition of manufacturing/processing in §§ 1.227 and 1.328 is not in conflict with the tentative conclusions FDA is reaching in this document. First, the general term ''treating'' refers broadly to treatments of any kind, and not specifically ''treating against pests.'' Under both the current definitions and the proposed revisions to the definitions, some ''treating'' (e.g., delivering a heat treatment) has been, and would continue to be, classified as manufacturing/processing outside the farm definition. Second, for a farm or farm mixed-type facility conducting operations on its own RACs, only those activities that do not satisfy either the

expanded definition of packing or holding, or the new definition of harvesting, would be classified as manufacturing/processing outside the farm definition. Thus, although application of a pesticide treatment to a farm's own RACs would now be classified within the farm definition when such treatment falls within the categories of holding or harvesting, application of a pesticide treatment off-farm has been, and would be continue to be, classified as manufacturing/processing outside the farm definition, because the exclusion applicable to a farm or farm mixed-type facility operating on its own RACs would not apply.

3. Coating a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities for Storage or Transport (e.g., Wax, Oil, or Resin Coatings)

FDA lists ''waxing'' as an example of a manufacturing/processing activity in the definition of that term in current §§ 1.227(b)(6) and 1.328, and waxing would remain as an example in the proposed revision to that definition. In addition, FDA has previously addressed ''waxing'' on farms and farm mixed-type facilities in the preamble to the interim final rule on Food Facility Registration (68 FR 58894 at 58912) and the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562 at 71587). In those documents, FDA previously concluded that on-farm waxing was manufacturing/processing outside the farm definition.

This previous conclusion that on-farm waxing was manufacturing/processing outside the farm definition would change for certain types of waxing under the proposed revisions to part 1. Under those proposed revisions, applying a coating to a farm or farm mixed-type facility's own RACs for the purpose of protecting them during storage or transport, and not to create a distinct commodity, would now be within the expanded definition of packing and thus be classified within the farm definition rather than be classified as manufacturing/processing outside the farm definition. Examples of such coatings are waxes, oils, and resins applied to fresh produce such as cucumbers, apples, and avocados. FDA is aware that such treatments are traditionally performed by farms to prepare crops for storage or transport. These coatings do not transform a RAC into a processed food. Thus, these treatments fit the proposed definition of ''packing'' applicable to farms and farm mixed-type facilities with respect to their own RACs. By contrast, if a farm or a farm mixed-type facility applies a coating to its own RACs in a manner that creates a distinct commodity (e.g., coating nuts in chocolate or coating apples in caramel), that activity would create a processed food and would not fit the expanded definition of packing. Thus, the act of applying the coating would continue to be classified as manufacturing/processing outside the farm definition.

Continuing to use ''waxing'' as an example in the proposed definition of manufacturing/processing in §§ 1.227 and 1.328 is not in conflict with these tentative conclusions. As explained with respect to pesticide treatments, activities that are conducted on a farm or farm mixed-type facility and are within the expanded definitions of packing and holding, or the new definition of harvesting, would be classified within the farm definition rather than classified as manufacturing/processing outside the farm definition. The current definition of manufacturing/processing in §§ 1.227(b)(6) and 1.328 and the examples of harvesting within the definition of farm in §§ 1.227(b)(3) and 1.328 demonstrate that FDA has consistently cited some activities as examples of manufacturing/processing as a general matter, but classified them differently in specific situations based on relevant circumstances. Washing, trimming, and cooling are all examples of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, but washing, trimming outer leaves of, and cooling produce are part of harvesting in the farm definition in current §§ 1.227(b)(3) and 1.328. Use of an activity as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, or the proposed revision of that definition, does not represent a conclusion that the activity is always classified as manufacturing/processing under all circumstances. FDA expects that its proposed revisions to part 1 will clarify this.

4. Drying a Farm or Farm Mixed-Type Facility's Own Raw Agricultural Commodities To Create a Distinct Commodity

FDA has previously addressed drying RACs on farms and farm mixed-type facilities in the Food Facility Registration Guidance (Ref. 116) and the Recordkeeping Guidance (Ref. 117). In those documents, FDA previously reached three conclusions relevant to drying: (1) Drying peppermint naturally during storage in a barn would not be manufacturing/processing; (2) drying hay naturally or artificially is an essential part of harvesting hay to prevent spontaneous combustion and is therefore not manufacturing/processing; and (3) drying alfalfa would be part of harvesting if it was an activity traditionally performed during the removing of the crop from the field through the safe storage of the crop.

One of these previous conclusions regarding drying (i.e., the previous conclusion regarding drying herbs) would change under the proposed revisions to part 1. As discussed in section VIII.D of this document, FDA tentatively concludes that the question of whether an activity transforms a RAC into a processed food should be part of defining what activities are within the farm definition, because RACs are essential products of farms and processed foods are not. Thus, activities that transform foods from RACs into processed foods would not be within the expanded definitions of packing or holding, or the new definition of harvesting, that apply to farms and farm mixed-type facilities conducting activities on their own RACs. Instead, anything that transforms a RAC into a processed food would be classified as manufacturing/processing outside the farm definition (unless it is done only for consumption on the farm or farm mixed-type facility).

In the Antimicrobial Guidance (Ref. 118), FDA approved of and referenced the 1996 EPA interpretive ruling entitled ''Pesticides; Status of Dried Commodities as Raw Agricultural Commodities'' (61 FR 2386). As discussed briefly in section VIII.D of this document, in the 1998 EPA/FDA Joint Policy Interpretation and the Antimicrobial Guidance, FDA and EPA concluded that a RAC becomes a processed food when it is dried, unless the purpose of the drying is to facilitate transportation or storage of the commodity prior to processing. As a practical matter, this means that some RACs become processed foods when they are dried, because the drying creates a distinct commodity from the RAC. An example of this kind of drying is drying grapes to create raisins; raisins are processed foods (61 FR 2386 at 2388). When the drying is for the purpose of storage or transport and does not create a distinct commodity, however (such as for grains, nuts, legumes, hays, other grasses, hops, rice, beans, and corn), the dried commodity remains a RAC (61 FR 2386 at 2388).

Accordingly, under the proposed revisions to part 1 drying hay and alfalfa would now be classified within the expanded definitions of packing or holding, depending on how the drying is conducted (before storage or during storage, respectively), because these crops are traditionally dried by farms for

the purpose of preparing for storage or transport (for packing) or for safe and effective storage (for holding), and because drying these crops does not create a distinct commodity (so the dried commodity is still a RAC). Drying hay and alfalfa in the manner FDA previously discussed would continue to be classified within the farm definition. In contrast, drying herbs such as peppermint would now be classified as manufacturing/processing outside the farm definition, because drying an herb creates a distinct commodity and therefore a processed food, just as drying a fruit creates a distinct commodity and therefore a processed food.

5. Off-Farm Packaging of Raw Agricultural Commodities

Current §§ 1.227(b)(8) and 1.328 define ''packaging'' (when used as a verb) as placing food into a container that directly contacts the food and that the consumer receives, and that definition of ''packaging'' would remain unchanged under the proposed revisions to the definitions in part 1. Packaging is listed as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328 (as well as in § 1.226(a)), and would continue to be listed as an example of manufacturing/processing under the proposed revisions to part 1. As discussed in section VIII.E.2 of this document, current §§ 1.227(b)(9) and 1.328 distinguish ''packaging'' from ''packing'' and define ''packing'' as placing food into a container other than packaging the food. Under the proposed revisions to the definitions in part 1, that definition of ''packing'' would be expanded to include activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act.

FDA has previously addressed packaging on farms and farm mixed-type facilities, and off-farm, in the Food Facility Registration Guidance (Ref. 116), the preamble to the Establishment and Maintenance of Records final rule (69 FR 71562 at 71587), and the Recordkeeping Guidance (Ref. 117). In those documents, FDA previously reached four conclusions relevant to ''packaging'' and ''packing'' activities on farms and farm mixed-type facilities: (1) Placing RACs into consumer-ready containers (e.g., placing strawberries in clamshell packages, and placing eggs in a carton) both on the farm that grew them and at off-farm packing houses is ''more akin to packing'' than packaging (despite meeting the definition of packaging) because it does not alter the form of the food, so it is not manufacturing/processing; (2) bottling wine (placing it in a container that touches the food and that the consumer receives) is packaging and therefore manufacturing/processing because it preserves the manufactured condition of the wine; (3) placing cereal in a plastic cereal box liner is packaging and therefore manufacturing/processing; and (4) placing apples received from elsewhere in bulk into plastic bags is packaging and therefore manufacturing/processing.

Most of these conclusions would remain the same under the proposed revisions to part 1, although the reasoning for those conclusions would instead be based on the organizing principles articulated in the proposed revisions to the definitions in part 1. Specifically, bottling wine and placing cereal in plastic box liners would continue to be classified as packaging and therefore manufacturing/processing, regardless of where such activities are performed, because those foods are processed foods to which the expanded proposed definition of packing would not be applicable. Placing apples received from elsewhere in bulk into plastic bags would continue to be classified as packaging and therefore manufacturing/processing, because the activity is conducted on others' RACs.

Under the proposed revisions to the definitions in part 1, a farm or farm mixed-type facility that places its own RACs in consumer containers that contact the food would now be classified as packing because farms traditionally do this to prepare their RACs for storage or transport, and this activity does not transform the RACs into a processed food. Examples of this kind of activity include an egg farm putting its own eggs in cartons, a strawberry farm placing its own strawberries in clamshell packages, or an apple farm placing its own apples into plastic bags. Such packing activities would continue to be classified within the farm definition.

Under the proposed revisions to part 1, there would be a change in how FDA considers the act of placing RACs into consumer containers (1) off-farm and (2) on a farm or farm mixed-type facility with respect to others' RACs. Off-farm, the expanded definition of packing would not apply, so this activity would be now be classified as packaging (and, therefore, manufacturing/processing). Off-farm, as a practical matter this change should have no practical impact because off-farm establishments that conduct this activity are already required to register under section 415 of the FD&C Act, and therefore already are subject to section 418 of the FD&C Act, whether this activity is classified as packing or manufacturing/processing. However, on a farm or farm mixed-type facility that places others' RACs into consumer containers, this activity would now be classified as packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm's own RACs. This change in classification would impact a farm or farm mixed-type facility that conducts such activities if it is not currently required to register. This classification result is consistent with the organizing principles articulated in section VIII.D of this document because, while it may be a practical necessity for a farm to place its own fragile RACs in consumer packages to protect them during storage and transport, packaging others' RACs is not part of the essential purpose of a farm (producing the farm's own RACs). Farms that conduct such activities are acting as distributors for another farm's products and FDA considers that the activities they conduct on others' RACs should be classified as manufacturing/processing, packing, or holding in the same manner as are activities performed by off-farm distributors of RACs. Therefore FDA tentatively concludes that these activities should now be outside the farm definition. We seek comment on this proposal.

6. Summary of Examples of the Impact of the Proposed Revisions to the Definitions in 21 CFR Part 1 on a Farm or Farm Mixed-Type Facility

For the convenience of the reader, Table 5 summarizes the examples discussed in sections VIII.F.2 through VIII.F.5 of this document.

TABLE 5—SUMMARY OF THE EXAMPLES OF THE IMPACT OF THE PROPOSED REVISIONS TO THE DEFINITIONS IN 21 CFR PART 1 ON A FARM OR FARM MIXED-TYPE FACILITY

Activity	How does FDA classify the activity under the *current* definitions in §§ 1.227 and 1.328?	Using FDA's *current* classification, would conducting the activity trigger the section 415 registration regulations?	How would FDA classify the activity under the *proposed* revisions to the definitions in §§ 1.227 and 1.328?	Using the classification under the *proposed* revised definitions, would conducting the activity trigger the section 415 registration regulations?	Would the classification under the *proposed* revised definitions represent a change?
Application of Pesticide					
Applying pesticides to own RACs prior to harvest.	Growing within the farm definition (because it is an integral part of growing crops).	No	Growing within the farm definition (because it is an integral part of growing crops).	No	No.
Fumigating own raw nuts to prevent insect infestation and damage during the potentially long storage period of the nuts.	Manufacturing/processing outside the farm definition (because application of pesticides after harvest is necessarily directed at the food, not the entire plant).	Yes	Holding within the farm definition (for the purpose of safe or effective storage).	No	Yes.
Use of pesticides in wash water applied to own RACs.	Harvesting within the farm definition if water is from a public or other supply chlorinated for other purposes, or if chlorine is added at 200 ppm or less (washing that does not treat the crop); manufacturing/processing outside the farm definition if chlorine is added at levels above 200 ppm.	Depends on source and level of chlorine in water; FDA has not previously addressed chemicals other than chlorine.	Harvesting within the farm definition (washing and/or treating against pests for the purpose of removing the crop from the growing area and preparing it for use as food).	No	Yes.
Coating					
Applying coatings to own RACs (e.g., applying waxes, oils, and resins to fresh produce; coating raw nuts in chocolate; coating apples in caramel).	Manufacturing/processing outside the farm definition (waxing generally, not specific to fresh produce).	Yes, for waxing generally; FDA has not previously addressed other coatings.	Waxes, oils, and resins on fresh produce: Packing within the farm definition (for the purpose of protecting them during storage or transport, and not to create a distinct commodity); Chocolate on nuts or caramel on apples: Manufacturing/processing outside the farm definition (creates a distinct commodity and thus creates a processed food).	Waxes, oils, and resins on fresh produce: No. Chocolate on nuts or caramel on apples: Yes	Yes.
Drying					
Drying peppermint naturally during storage in a barn.	Storage within the farm definition.	No	Manufacturing/processing outside the farm definition (transforms a RAC into a processed food).	Yes	Yes.

TABLE 5—SUMMARY OF THE EXAMPLES OF THE IMPACT OF THE PROPOSED REVISIONS TO THE DEFINITIONS IN 21 CFR PART 1 ON A FARM OR FARM MIXED-TYPE FACILITY—Continued

Activity	How does FDA classify the activity under the *current* definitions in §§ 1.227 and 1.328?	Using FDA's *current* classification, would conducting the activity trigger the section 415 registration regulations?	How would FDA classify the activity under the *proposed* revisions to the definitions in §§ 1.227 and 1.328?	Using the classification under the *proposed* revised definitions, would conducting the activity trigger the section 415 registration regulations?	Would the classification under the *proposed* revised definitions represent a change?
Drying hay naturally or artificially.	Harvesting within the farm definition (an essential part of harvesting hay to prevent spontaneous combustion).	No	Packing or holding within the farm definition (depending on whether the drying is before storage or during storage).	No	No.
Drying alfalfa	Harvesting within the farm definition (traditionally performed during the removing of the crop from the field through the safe storage of the crop).	No	Packing within the farm definition (done before storage to prepare a RAC for storage or transport and does not create a distinct commodity).	No	No.
Drying grapes to create raisins.	FDA has not previously addressed this activity.	FDA has not previously addressed this activity.	Manufacturing/processing outside the farm definition (transforms a RAC into a processed food).	Yes	Yes (because FDA is addressing this activity for the first time).
Packing/Packaging					
Bottling wine	Packaging, which is manufacturing/processing outside the farm definition (because it preserves the manufactured condition of the wine).	Yes	Packaging, which is manufacturing/processing outside the farm definition (because the food is a processed food so the expanded definition of packing does not apply).	Yes	No.
Placing cereal in a plastic cereal box liner.	Packaging, which is manufacturing/processing outside the farm definition.	Yes	Packaging, which is manufacturing/processing outside the farm definition (because the food is a processed food so the expanded definition of packing does not apply).	Yes	No.
Placing a farm's or farm mixed-type facility's own RACs into consumer-ready containers (e.g., placing strawberries in clamshell packages, and placing eggs in a carton).	Packing within the farm definition (because it does not alter the form of the food).	No	Packing within the farm definition (because farms traditionally do this to prepare their RACs for storage or transport, and this activity does not transform the RACs into a processed food).	No	No.
Placing others' RACs into consumer-ready packages on a farm or farm mixed-type facility (e.g., placing others' apples received in bulk into plastic bags).	Packaging, which is manufacturing/processing outside the farm definition.	Yes	Packaging, which is manufacturing/processing outside the farm definition (because the activity is conducted on others' RACS).	Yes	No.

TABLE 5—SUMMARY OF THE EXAMPLES OF THE IMPACT OF THE PROPOSED REVISIONS TO THE DEFINITIONS IN 21 CFR PART 1 ON A FARM OR FARM MIXED-TYPE FACILITY—Continued

Activity	How does FDA classify the activity under the *current* definitions in §§ 1.227 and 1.328?	Using FDA's *current* classification, would conducting the activity trigger the section 415 registration regulations?	How would FDA classify the activity under the *proposed* revisions to the definitions in §§ 1.227 and 1.328?	Using the classification under the *proposed* revised definitions, would conducting the activity trigger the section 415 registration regulations?	Would the classification under the *proposed* revised definitions represent a change?
Placing others' RACs into consumer-ready containers off-farm (e.g., placing strawberries in clamshell packages, and placing eggs in a carton at a facility not co-located on a farm or farm mixed-type facility).	Packing (because it does not alter the form of the food), but not within the farm definition because conducted off-farm.	Yes	Packaging, which is manufacturing/processing (because the activity is conducted off-farm, so the expanded definition of packing does not apply).	Yes	Yes, but while the classification of the activity changes from packing to manufacturing/processing, under both the current and proposed revised definitions, the activity would trigger registration.

G. Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

As discussed in section VIII.A.2 of this document, section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.''

As used in section 103(c)(1) of FSMA, the term ''risk analysis'' is ambiguous. One interpretation is that the common meaning of the term is intended—a simple evaluation of whether activity/food combinations are likely to result in the consumer becoming ill. Another interpretation is that the ''risk analysis'' should be consistent with the formal definition and related terms used by Codex with respect to food safety (Ref. 119):

- Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
- Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.
- Risk assessment is a scientifically-based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.
- Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Because section 103(c)(1)(C) of FSMA calls for a science-based risk analysis, we are applying the Codex definitions to the extent possible. It is not clear whether the requirement of section 103(c)(1)(C) of FSMA to conduct a science-based risk analysis was intended to encompass all three components of risk analysis. Section 103(c)(1)(D) of FSMA requires the Secretary to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act, including hazard analysis and preventive controls, and the mandatory inspection frequency of section 421, or to modify those requirements for facilities engaged in on-farm manufacturing, processing, packing or holding activities determined to be low risk involving foods determined to be low risk. Thus, section 103(c)(1)(D) of FSMA is focused on ensuring that the agency's risk management decisions with respect to exempting or modifying requirements applicable to low-risk on-farm activity/food combinations under sections 418 and 421 are science-based, as determined by an analysis of the risk of specific types of on-farm activity/food combinations required by section 103(c)(1)(C). We therefore tentatively conclude that the analysis required by section 103(c)(1)(C) should be limited to an assessment of the risk of specific types of on-farm activity/food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D). The risk communication component of the risk analysis is accomplished through the discussion of that assessment in this document, the opportunities for public comment (on the risk assessment and on this proposed rule), and our evaluation of, and response to, comments in a final rule.

Consistent with this approach, we conducted a qualitative risk assessment (Ref. 115) (''Section 103(c)(1)(C) draft RA'') related to activity/food combinations for the purpose of determining which activity/food combinations would be considered low risk. We focused on activity/food combinations that we identified as being conducted on farms (and, thus, might be conducted by farm mixed-type facilities), but we did not consider activity/food combinations that would be solely within the farm definition (such as growing fruits and vegetables) and, thus, are not relevant to the requirements of section 103 of FSMA. We focused on considering the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so better enabled us to focus on whether

a specific manufacturing, processing, packing, or holding activity conducted on food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act.

Elsewhere in this issue of the **Federal Register**, FDA is making the section 103(c)(1)(C) draft RA available for public comment. We will consider comments regarding the section 103(c)(1)(C) draft RA in preparing a final version of the RA and will announce the availability of the final version of the RA when it is available. The final preventive controls rule will take into account the final version of the section 103(c)(1)(C) RA.

H. Results of the Qualitative Risk Assessment

In this section, we report the results of the section 103(c)(1)(C) draft RA, arranged in three lists. References to ''farms'' in these lists should be understood to include farm mixed-type facilities. The lists are shaped by the proposed definitions for harvesting, manufacturing/processing, packing, or holding in the section 415 registration regulations (discussed in section VIII.E of this document), the organizing principles (discussed in section VIII.D of this document) that form the basis for those proposed definitions, and the examples of activity classifications (discussed in section VIII.F of this document). As discussed in section VIII.E of this document, the same activity may be classified differently (among the categories of harvesting, manufacturing/processing, packing, or holding) depending on whether the food being operated upon is a RAC and whether the RAC was grown or raised on the farm or farm mixed-type facility performing the activity or a farm under the same ownership. We request comment on the lists in sections VIII.H.1 through VIII.H.3.

For the purposes of this document, a fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. For the purposes of this document, a vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Examples of fruits and vegetables are apples, apricots, avocados, bananas, berries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus, cucumbers, garlic, grapes, green beans, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, mushrooms, onions, papaya, peaches, pears, peas, peppers, pineapple, plums, radish, scallions, snow peas, spinach, sprouts, squash, tomatoes, and watermelon. For the purposes of this document, grains means the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans.

For the purpose of the section 103(c)(1)(C) draft RA, ''intact fruits and vegetables'' refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts. Cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts can be considered part of ''fruits and vegetables'' as a general matter, but we addressed those foods separately for the purpose of section 103(c)(1)(C) draft RA in order to accurately reflect differences in activity/food combinations likely to be performed on farm mixed-type facilities on those foods as compared to other fruits and vegetables, as well as specific hazards associated with certain of those foods.

1. List of Low-Risk On-Farm Packing and Holding Activity/Food Combinations When Conducted on Food Not Grown, Raised, or Consumed on That Farm or Another Farm Under the Same Ownership

The section 103(c)(1)(C) draft RA identified the following low-risk packing and holding activity/food combinations when conducted on a farm on food not grown, raised, or consumed on that farm or another farm under the same ownership—i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- Hard candy, fudge, taffy, and toffee;
- Cocoa products;
- Cocoa beans and coffee beans (raw or roasted);
- Grains and grain products;
- Honey (raw and pasteurized);
- Intact fruits and vegetables;
- Jams, jellies and preserves;
- Maple sap for syrup and maple syrup;
- Peanuts and tree nuts;
- Soft drinks and carbonated water; and
- Sugar beets, sugarcane, and sugar.

We note that the same activities performed on a farm's own RACs, or food consumed on the farm or another farm under the same ownership, would be within the farm definition and therefore were outside the scope of the section 103(c)(1)(C) draft RA.

2. List of Low-Risk On-Farm Manufacturing/Processing Activity/Food Combinations When Conducted on the Farm's Own Raw Agricultural Commodities for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/food combinations when conducted on a farm on the farm's own RACs for distribution into commerce:

- Artificial ripening of intact fruits and vegetables;
- Boiling/evaporation of maple sap to make maple syrup;
- Chopping raw peanuts and raw tree nuts;
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and raw peanuts and raw tree nuts (e.g., adding seasonings);
- Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);
- Extracting oil from grains;
- Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making sugar from sugarcane and sugar beets; and
- Salting raw peanuts and raw tree nuts.

3. List of Low-Risk On-Farm Manufacturing/Processing Activity/Food Combinations When Conducted on Food Other Than the Farm's Own Raw Agricultural Commodities, for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/food combinations when conducted on a

farm on food other than the farm's own RACs, for distribution into commerce.

- Artificial ripening of intact fruits and vegetables;
- Chopping peanuts and tree nuts;
- Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and peanuts and tree nuts (e.g., adding seasonings);
- Cooling intact fruits and vegetables using cold air;
- Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
- Extracting oils from grains (e.g., corn, oilseeds, soybeans);
- Fermenting cocoa beans and coffee beans;
- Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
- Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;
- Making hard candy, fudge, taffy, and toffee;
- Making cocoa products from roasted cocoa beans;
- Making honey;
- Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- Making maple syrup;
- Making soft drinks and carbonated water;
- Making sugar from sugar beets and sugarcane;
- Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
- Packaging hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
- Salting peanuts and tree nuts;
- Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
- Sifting grains and grain products;
- Sorting, culling and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets and sugarcane;
- Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation); and
- Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

We note that the list in this section (i.e., section VIII.H.3) for low-risk manufacturing/processing activity/food combinations for foods other than a farm's own RACs is longer than the corresponding list in the previous section (i.e., section VIII.H.2) for low-risk manufacturing/processing activity/food combinations for a farm's own RACs. This relates to the fact that some activities that would be manufacturing/processing when performed on foods other than a farm's own RACs are not manufacturing/processing when performed on a farm's own RACs. As discussed in sections VIII.E and VIII.F of this document, when some activities are performed on the farm's own RACs, those activities are classified as packing, holding, or harvesting and are within the farm definition, making them outside the scope of the section 103(c)(1)(C) draft RA and resulting in a shorter list of low-risk activity/food combinations for the purpose of the rulemaking required by section 103(c) of FSMA.

I. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 418 of the FD&C Act

Based on the results of the section 103(c)(1)(C) draft RA regarding on-farm low-risk activity/food combinations, we are proposing in § 117.5(g) and (h) to exempt farm mixed-type facilities that are small or very small businesses (as defined in proposed § 117.3) from requirements under section 418 of the FD&C Act if the only activities subject to section 418 that the business conducts are low-risk activity/food combinations (see the discussion of these proposed exemptions in section X.C.6 of this document). The proposed exemptions would not exempt eligible facilities from the requirement to register under section 415 of the FD&C Act.

J. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Food Combinations Under Section 421 of the FD&C Act

We tentatively conclude that FDA should consider the low-risk on-farm activity/food combinations identified in the section 103(c)(1)(C) draft RA as a factor in identifying high-risk facilities that are small and very small businesses and allocating inspection resources under Section 421 of the FD&C Act, Targeting of Inspectional Resources for Domestic Facilities. However, at this time, FDA tentatively concludes that it should not exempt or modify the frequency requirements under 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business. Current data limitations impact our ability to accurately identify such facilities, and we must be able to identify such facilities in order to implement an exempted or modified inspection frequency schedule. We request comment on whether we should establish data submission requirements that would allow us to identify these types of facilities in order to exempt them from the inspection frequencies, or modify the inspection frequencies that apply to them, under section 421 of the FD&C Act. Examples of data elements that we might need in order to identify these facilities include: Identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, food category/activity type. We also request comment on these possible data elements and any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

IX. Proposed General Revisions to Current Part 110

A. Title

FDA is proposing to revise the title of current subpart B from ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food'' to ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' The proposed title would reflect that proposed part 117 would include both CGMP requirements (including those established prior to the enactment of FSMA) and requirements for risk-based preventive controls for domestic and

foreign facilities that are required to register under section 415 of the FD&C Act. As proposed, the title of proposed part 117 would no longer identify specific activities (i.e., manufacturing, packing, and holding). The activities covered by the CGMP requirements would be identified within the requirements themselves and are not necessary to include in the title of proposed part 117. We request comment on the proposed title for part 117.

B. Proposed Redesignations

FDA is proposing to redesignate the subparts of current part 110 and to include in proposed part 117, subpart B the CGMP provisions already established in part 110. The proposed redesignation will clearly separate current CGMP requirements, and any newly proposed CGMP requirements, from newly proposed requirements that would implement section 418 of the FD&C Act. The proposed redesignation is intended to make it easy for persons who would be exempt from requirements established under section 418 of the FD&C Act to identify the CGMP requirements that apply to them.

FDA also is proposing a general reorganization and redesignation of the provisions currently in part 110 as they would be established in proposed part 117. The proposed revisions are intended to enhance the clarity of proposed part 117 as a whole. Table 6 shows the proposed reorganization and redesignation of current provisions. In sections X and XI of this document, we discuss proposed changes to the current provisions of part 110 in the order in which they would appear in a final rule based on this proposed rule. Provisions that we do not propose to delete or revise would be re-established in part 117 unchanged.

TABLE 6—PROPOSED REARRANGEMENT OF PROVISIONS AND SUBPARTS OF CURRENT PART 110

Current designation	Current subpart location	Proposed redesignation	Proposed subpart location
§ 110.3—Definitions	Subpart A	Proposed § 117.3	Proposed Subpart A.
§ 110.5—Current good manufacturing practice	Subpart A	Proposed § 117.1	Proposed Subpart A.
§ 110.10—Personnel	Subpart A	Proposed § 117.10	Proposed subpart B.
§ 110.19—Exclusions	Subpart A	Proposed § 117.5(k)	Proposed subpart A.
§ 110.20—Plant and grounds	Subpart B	Proposed § 117.20	Proposed subpart B.
§ 110.35—Sanitary operations	Subpart B	Proposed § 117.35	Proposed subpart B.
§ 110.37—Sanitary facilities and controls	Subpart B	Proposed § 117.37	Proposed subpart B.
§ 110.40—Equipment and utensils	Subpart C	Proposed § 117.40	Proposed subpart B.
§ 110.80—Processes and controls	Subpart E	Proposed § 117.80	Proposed subpart B.
§ 110.93—Warehousing and distribution	Subpart E	Proposed § 117.93	Proposed subpart B.
§ 110.110—Natural or unavoidable defects in food for human use that present no health hazard.	Subpart G	Proposed § 117.110	Proposed subpart B.

C. Proposed Revisions for Consistency of Terms

1. Activities Subject to Proposed Part 117

FDA is proposing to revise provisions of current part 110 to make clear that the activities that would be subject to proposed part 117 include manufacturing, processing, packing and holding. We describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision. Section 418 of the FD&C Act uses this group of terms to broadly identify activities that take place in food facilities. In addition, we have previously described activities that may be considered ''manufacturing, processing, packing, or holding'' by establishing definitions for ''manufacturing/processing'' in current §§ 1.227(b)(6) and 1.328, ''packing'' in current §§ 1.227(b)(9) and 1.328, and ''holding'' in current §§ 1.227(b)(5) and 1.328. This proposed rule proposes certain revisions to these existing definitions (see section VIII.E of this document) and would incorporate the revised definitions of manufacturing/processing, packing, and holding in proposed part 117. We tentatively conclude there is no meaningful distinction between ''manufacturing/processing,'' ''packing,'' and ''holding'' as defined in our proposed revisions to §§ 1.227 and 1.328 and those terms as they have been used in current part 110. We also tentatively conclude that consistent use of these terms throughout proposed part 117, in reference to activities taking place in food facilities, establishments, or plants, would make the regulations more clear and have no substantive effect on the current requirements. We request comment on this proposed revision.

2. The Term ''Facility''

FDA is proposing to replace the term ''facility'' or ''facilities'' in current part 110 with the term ''establishment'' or ''plant'' in proposed part 117 whenever the term ''facility'' or ''facilities'' could be confused with the firms that are subject to the proposed requirements for hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. FDA is proposing this change to distinguish between the requirements of current part 110 (Current Good Manufacturing Practices) and requirements that we are proposing to establish under section 103 of FSMA. The term ''facility'' as used in current part 110 reflects the common meaning of that term as something designed, built, or installed to serve a specific function. However, after issuance of current part 110, in our regulation implementing section 415 of the FD&C Act, ''Registration of Food Facilities'' (§ 1.227(b)(2) in part 1, subpart H), we defined the term ''facility'' to have a very specific meaning for the purpose of that regulation as follows:

Current section 1.227(b)(2) provides in part that ''[f]acility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.'' Part 1, subpart H broadly defines the term ''facility'' for the purposes of that subpart, and provides that facilities must register unless they qualify for one of the exemptions in that subpart. For example, current § 1.227(b)(3) defines ''farm'' as a type of facility, and § 1.226(b) provides that farms do not need to register.

Section 418(o)(2) of the FD&C Act defines ''facility'' for the purposes of section 418 to mean ''a domestic facility or a foreign facility that is required to register under section 415'' of the FD&C Act, and proposed § 117.3 would define ''facility'' to incorporate this statutory

definition. Under proposed § 117.3, the term ''facility'' would have a meaning for the purposes of proposed part 117 that is more narrow than the common meaning of the term or the definition of facility in current § 1.227(b)(2), in that it would encompass only those facilities that are required to register under section 415 of the FD&C Act (and part 1, subpart H). Our proposal to replace the term ''facility'' in current part 110 with ''establishment'' or ''plant'' in proposed part 117 is intended to avoid confusion about the applicability of proposed part 117 to plants or establishments that satisfy the definition of the term ''facility'' in current § 1.227(b) but are exempt from the requirement to register. We describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision. We request comment on this proposed revision.

We are not proposing to replace the use of the term ''facilities'' in current requirements directed to specific functional parts of a plant or establishment, such as ''toilet facilities'' and ''hand-washing facilities.'' We tentatively conclude that the use of the term ''facilities'' in these contexts would not create confusion. We request comment on whether there is potential for confusion such that we should eliminate all use of the term ''facility'' or ''facilities'' as it is used in current part 110 irrespective of context.

3. Owner, Operator, or Agent in Charge

Section 418 of the FD&C Act establishes requirements applicable to the ''owner, operator, or agent in charge'' of a facility. Current part 110 establishes requirements for persons not explicitly identified as ''owner, operator, or agent in charge'' of a food plant or establishment. For example, current § 110.10 establishes requirements applicable to ''plant management'' and current § 110.20(a) establishes requirements for the ''operator'' of a food plant. We request comment on whether there is any meaningful difference between the persons identified in current part 110 and the ''owner, operator, or agent in charge'' identified in section 418 of the FD&C Act. We also request comment on whether it would be appropriate to refer to the ''owner, operator, or agent in charge'' of a plant, establishment, or facility throughout proposed part 117 and, if so, whether the requirements would be clear if we revise the proposed rule to use pronouns (such as ''you'' and ''your'') within proposed part 117. Pronouns are commonly used in contemporary regulations and simplify the presentation of the requirements.

4. Food-Packaging Materials

Most provisions of current part 110 directed to preventing contamination of food and food-contact substances also are directed to preventing contamination of food-packaging materials. Because food-packaging materials come in contact with food, if they become contaminated this could lead to contamination of the food. FDA is proposing that provisions of current part 110 directed to preventing contamination of food and food-contact substances consistently be directed to preventing contamination of food-packaging materials as well. We describe each of these proposed revisions elsewhere in this document, in an order consistent with the placement of the current or revised provision.

D. Proposed Additions Regarding Cross-Contact

Proposed § 117.3 would define the term ''cross-contact'' to mean the unintentional incorporation of a food allergen into a food. ''Food allergen'' would be defined as a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. As discussed in section X.B.4 of this document, it has been estimated that food allergies affect four to six percent of children and two to three percent of adults in the U.S. Food allergies can cause life threatening reactions to foods. Because there is no cure for food allergy, sensitive consumers and their families must practice avoidance to prevent reactions. To do so they must rely on food labels to be complete, clear, and accurate. Manufacturers can provide consumers with the food labels they need by using controls to ensure that labels declare all the food allergens that are intended to be present, controls to ensure that the correct label is applied to the product, and controls that prevent the unintended presence of food allergens through cross-contact.

Comments submitted to the Food CGMP Modernization Working Group emphasized the importance of controls to prevent cross-contact (Ref. 1). After considering the comments, the CGMP Working Group report recommended that food processing establishments that handle any of the major food allergens be required to develop and adopt a food allergen control plan that addresses six areas of control, one of which is ''[p]revention of cross-contact during processing'' (Ref. 1). FDA interprets current part 110 to require protection against cross-contact, which can constitute insanitary conditions that may cause a food to be adulterated under section 402(a)(4) of the FD&C Act if the food may have been rendered injurious to health. Consistent with this interpretation, FDA issued a Notice to Manufacturers titled ''Allergy Warning Letter'' on June 10, 1996, advising with regard to cross-contact that adhering to CGMPs is essential for effective reduction of adverse reactions, and urging manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of unintended food allergens (Ref. 120). In the past, inadvertent incorporation of an allergen into a food was referred to as ''contamination'' or ''cross contamination'' (Ref. 121), and in many instances these terms are still used (Ref. 122). More recently, the term ''cross-contact'' (rather than ''contamination'' or ''cross contamination'') has been applied with respect to unintentional transfer of allergenic proteins from a food containing the proteins to one that does not (Ref. 123) (Ref. 124), because an allergen is a normal component of food, and not itself a contaminant. Given this shift in the scientific literature distinguishing ''cross-contact'' from ''contamination'' and ''cross contamination,'' FDA tentatively concludes that it should begin using the term ''cross-contact'' to describe inadvertent incorporation of an allergen into food, rather than the general term ''contamination,'' for purposes of clarity. To make it clear that CGMPs require protection against cross-contact, and to ensure that CGMPs continue to address health concerns related to allergens, FDA is proposing to revise several provisions of current part 110 to explicitly address cross-contact in proposed part 117.

We describe each of these proposed additions elsewhere in this document, in an order consistent with the placement of the current or revised provision. We request comment on this proposed revision to the CGMPs.

E. Proposed Revisions for Consistency With the Definition of ''Food''

Current § 110.3 defines ''food'' to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients. We are proposing to retain that definition in this proposed rule. There is an overlap between raw materials and ingredients. Not all raw materials are ingredients. For example, under section 201(f) of the FD&C Act, a food additive is food and, thus, the manufacture of a food additive is subject to current part 110. An example of a food additive is sucrose

fatty acid esters. Under § 172.859, sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters. The regulation for sucrose fatty acid esters identifies a number of raw materials used in the production of sucrose fatty acid esters. Because the production process transforms those raw materials into the substance ''sucrose fatty acid esters,'' those raw materials generally would not be viewed as ''ingredients'' of the final chemical product. Likewise, if a facility adds the food additive ''sucrose fatty acid esters'' to a food product, the facility would view that food additive as an ingredient of its food product, but would not view the chemicals used to produce sucrose fatty acid esters as ingredients of its food product.

The title of current § 110.80(a) and several provisions within current § 110.80 refer to ''raw materials and other ingredients'' rather than to ''raw materials and ingredients'' as in the definition of ''food.'' For consistency with the definition of food, we are proposing to change the title of current § 110.80(a) (which would be proposed § 117.80(b)) to ''Raw materials and ingredients.'' As a companion change to this change in title, we are proposing to substitute ''ingredients'' for ''other ingredients'' throughout provisions in current § 110.80 that refer to both raw materials and ingredients. We do not list every instance where this proposed revision would apply in proposed § 110.80.

F. Proposed Revisions To Address Guidance in Current Part 110

In 2000, we codified our policies and procedures for the development, issuance, and use of guidance documents in § 10.115 (21 CFR 10.115) (65 FR 56468, September 19, 2000). Under § 10.115(b), guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe our interpretation of or policy on a regulatory issue. They include documents that relate to the design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies. Under § 10.115(d), guidance documents do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA.

Comments submitted to the Food CGMP Modernization Working Group noted that several provisions of current part 110 use non-binding language such as ''should'' and recommended that we revise part 110 to express all provisions using binding language (e.g., ''shall'' in place of ''should'') (Ref. 1). Consistent with these comments and with 21 CFR 10.115, we are proposing to delete some non-binding provisions of current part 110 (e.g., provisions using ''should'' or ''compliance may be achieved by''). We request comment on this proposal. In section XI.M of this document, we request comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or to simply retain them as useful provisions of a comprehensive CGMP. We describe each of these in more detail elsewhere in this document.

G. Proposed Editorial Changes

FDA is proposing to revise current part 110 to make several changes that are editorial in nature. These editorial changes have no substantive effect on the current requirements of part 110 and, thus, we do not list every instance where these proposed editorial changes would apply. We are proposing to:

- Refer to the ''Federal Food, Drug, and Cosmetic Act'' rather than to ''the act'' for clarity and for consistency with our current approach to citing the FD&C Act in new regulations;
- Replace the term ''shall'' with the term ''must.'' The term ''must'' is a more common word than ''shall,'' and we are using ''must'' in new regulations.
- Replace the phrase ''includes, but is not limited to'' with ''includes,'' because the use of the word ''includes'' indicates that the specified list that follows is not exclusive. The phrase ''but is not limited to'' is unnecessary. (72 FR 34752 at 34765, June 25, 2007)
- Replace the phrase ''adulteration within the meaning of the act'' with the single term ''adulteration'' because ''within the meaning of the act'' is not needed for the term ''adulteration'' to have the meaning assigned by section 402 of the FD&C Act (21 U.S.C. § 342 (Adulterated food).
- Replace the term ''whenever'' with ''when'' for grammatical simplicity.

X. Proposed Revisions to General Provisions of Part 110 (Proposed Part 117, Subpart A)

A. Proposed § 117.1—Applicability and Status

FDA is proposing to redesignate current § 110.5(a) as proposed § 117.1(a) with associated editorial changes described in section IX.G of this document. Current § 110.5(a) establishes that the criteria and definitions in part 110 apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Current § 110.5(a) also establishes that the criteria and definitions in part 110 apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). FDA is proposing to retain the provisions of current § 110.5(a) in proposed § 117.1(a). The provisions of current § 110.5(a) as re-established in proposed § 117.1(a) would continue to apply to all provisions that currently are established in part 110 and would be re-established in proposed part 117. Under this proposed rule, proposed § 117.1 also would apply to new provisions of proposed part 117, including provisions that would be added under the authority of sections 402(a)(3), 402(a)(4), or 418 of the FD&C Act, section 361 of the PHS Act, or a combination of those authorities. We note that section 418(a) of the FD&C Act provides that facilities subject to that section must ''identify and implement preventive controls to * * * provide assurances that * * * food is not adulterated under section 402 [of the FD&C Act]'' and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 418(c) and (e). In section III of this document, we explain how the proposed provisions are necessary to protect against contamination with hazards that may adulterate food. We tentatively conclude that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 117 in determining whether, under particular circumstances, a food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act.

Section 103(e) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding a new section—(uu)—to the list of acts and the causing thereof that are prohibited. Under section 301(uu), the following act, and the causing thereof, is prohibited: ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' To clearly communicate that failure to comply with regulations established under section 418 is a prohibited act, proposed § 117.1(b) would establish that the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C, D, E, or F of part 117 is a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)).

FDA is proposing to redesignate current § 110.5(b) as proposed § 117.1(c) with no changes. Current § 110.5(b) establishes that food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations. As discussed in sections II.A.1 and II.A.2 of this document, following the establishment of the umbrella CGMPs in 1969 (34 FR 6977), FDA established additional CGMP requirements, including CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979; currently established in part 113) and CGMP requirements for acidified foods (proposed rule, 41 FR 30457, July 23, 1976; final rule, 44 FR 16230, March 16, 1979; currently established in part 114). In the preamble to the proposed rule to establish current § 110.5(b), we explained that this provision was intended to communicate that foods covered by such specific CGMPs are still subject to part 110 (44 FR 33238, at 33239, June 8, 1979). Since current § 110.5(b) was established, we have established additional food safety regulations, such as the 1995 HACCP regulations in part 123 for fish and fishery products (60 FR 65096, December 18, 1995) and the 2001 HACCP regulations in part 120 for juice (66 FR 6138, January 19, 2001). As with foods that are subject to part 113 or part 114, foods that are subject to part 123 or part 120 are subject to the requirements of part 123 or 120 even though they are foods covered by the current good manufacturing practice requirements that are currently established in part 110 and would be re-established in part 117. See section II.A of this document for a discussion of other food safety regulations for specific foods to which this would also apply.

Importantly, section 418 of the FD&C Act requires that we establish regulations to implement requirements for hazard analysis and risk-based preventive controls for human food. As discussed in section V of this document, we tentatively conclude that it is appropriate to establish these requirements for hazard analysis and risk-based preventive controls within the framework of current part 110, as would be re-established in proposed part 117. As discussed in section IX.A of this document, we are proposing that the title of proposed part 117 reflect the addition of these new requirements. As discussed more fully in section X.C of this document, section 418 of the FD&C Act establishes several exemptions from the proposed requirements for hazard analysis and risk-based preventive controls. For example, section 418(j)(1) of the FD&C Act provides that section 418 of the FD&C Act ''shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with * * * (A) [t]he Seafood Hazard Analysis Critical Control Points Program * * *'' (We interpret ''Seafood Hazard Analysis Critical Control Points Program'' to mean the requirements of part 123 for fish and fishery products.) As discussed below, consistent with section 418(j)(1)(A), proposed § 117.5(b) would provide that proposed subpart C of proposed part 117 would not apply with respect to activities that are subject to part 123 at a facility, if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with part 123. However, under current § 110.5(b) and proposed § 117.1(c), all activities at that facility have been, and would continue to be, subject to the CGMP requirements in proposed subpart B and the requirements of part 123. The same would be true for establishments and facilities that are subject to other food safety regulations, consistent with the exemptions that would be established in proposed § 117.5.

B. Proposed § 117.3—Definitions

1. Redesignation

FDA is proposing to redesignate all definitions in current § 110.3(a) through (r) as proposed § 117.3, eliminate paragraph designations (such as (a), (b), and (c)), and add new definitions in alphabetical order. Paragraph designations are not necessary when the definitions are presented in alphabetical order. Proposed § 117.3 would remain within subpart A.

2. Current Definitions That FDA Is Proposing To Delete

Current § 110.3(p) defines ''shall'' to be used to state mandatory requirements. FDA is proposing to delete the definition of ''shall'' and use ''must'' instead, as discussed in section IX.G of this document.

3. Current Definitions That FDA Is Proposing To Revise

Current § 110.3(e) defines ''critical control point'' to mean a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food. Current § 110.3(e) was established in 1986. Current § 110.3(e) preceded various currently used definitions of ''critical control point'' (CCP)—e.g., in the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood (part 123), juice (part 120), and meat and poultry (9 CFR part 417). Proposed § 117.3 would revise the current definition of ''critical control point'' to match the statutory definition in section 418(o)(1) of the FD&C Act and to be consistent with definitions in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Proposed § 117.3 would define ''critical control point'' to mean a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

A non-substantive difference between the definition of CCP in proposed § 117.3 and the definition of CCP in § 120.3(d) is that proposed § 117.3 would incorporate the phrase ''food safety hazard'' into the definition of CCP, whereas § 120.3(d) uses the phrase ''food hazard.'' We see no meaningful difference between ''food safety hazard'' and ''food hazard,'' whether comparing proposed § 117.3 to § 120.3(d) or whether comparing § 120.3(d) to § 123.3(b) (which uses the phrase ''food safety hazard'' in its definition of CCP). In fact, we see no meaningful difference between ''food safety hazard'' and ''hazard'' and are proposing to define the term ''hazard'' rather than ''food safety hazard'' for the purpose of proposed part 117 (see the discussion of our definition of the term ''hazard'' in

section X.B.4 of this document). Section 418 of the FD&C Act largely refers to ''hazards'' and the single reference to ''food safety hazard'' is in the statutory definition of CCP. Because the phrase ''food safety hazard'' appears in so many current definitions of CCP, we tentatively conclude it is appropriate to propose to establish the statutory definition of CCP into the proposed rule, even though this will be the only place in the proposed rule where we use the term ''food safety hazard.''

There are slight differences in wording among the various currently used definitions of CCP—e.g., whether the definition uses the term ''control'' or the phrase ''control measure'' and in how the definition incorporates concepts such as ''essential,'' ''preventing,'' eliminating'' or ''reducing to acceptable level'' hazards. Part 123 preceded the 1998 NACMCF guidelines and, thus, has the most differences. For the purpose of this proposed rule, we do not see these differences as meaningful and tentatively conclude that the statutory definition of CCP in section 418(o)(1) of the FD&C Act is, for practical purposes, consistent with existing definitions and that our proposed definition of CCP would present no conflict with existing recommendations.

The definition of CCP in proposed § 117.3 would also differ from the definition of CCP in current § 110.3(e) in that the definition of CCP would no longer explicitly address filth. Deleting filth from the definition of CCP is consistent with section 418(o)(1) of the FD&C Act, and with the various current definitions of CCP, to emphasize food safety hazards generally rather than specifically identifying filth, which may or may not present a food safety hazard, depending on the circumstances. Similarly, the definition of CCP in proposed § 117.3 also would no longer explicitly address decomposition of the final food. However, section 418(b)(1) of the FD&C Act refers to decomposition among the hazards to be identified and evaluated and, thus, decomposition is considered within the term ''hazard'' when it affects the safety of the product.

Current § 110.3(g) defines ''food-contact surfaces'' as those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Current § 110.3(g) also specifies that ''food-contact surfaces'' includes utensils and food-contact surfaces of equipment. FDA is proposing to revise the definition for ''food-contact surfaces'' to include the phrase ''or other transfer'' after ''drainage.'' FDA is proposing this revision to clarify that surfaces from which any transfer involving liquids or non-liquids onto the food or onto surfaces that contact the food are food-contact surfaces. Proposed § 117.3 would define ''food-contact surfaces'' to mean those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Proposed § 117.3 would also specify that ''food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

Current § 110.3(i) defines ''microorganisms'' to mean yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. Current § 110.3(i) also specifies that the term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Current § 110.3(i) also states that, occasionally in these regulations, FDA used the adjective ''microbial'' instead of using an adjectival phrase containing the word microorganism. FDA is proposing to revise the definition for ''microorganisms'' to also include protozoa and microscopic parasites. FDA is proposing this revision to clarify that FDA considers not only yeasts, molds, bacteria and viruses, but also protozoa and microscopic parasites, to be microorganisms of importance in the safe and sanitary production of foods. As discussed in section IX.G of this document, FDA is proposing to delete the phrases ''but is not limited to,'' and ''within the meaning of the act.'' FDA also is proposing to delete the last sentence in the definition because it is not needed. Proposed § 117.3 would define ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. Proposed § 117.3 would also specify that the term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Current § 110.3(k) defines ''plant'' to mean the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food. FDA is proposing to revise the definition for ''plant'' by adding ''processing'' and ''packing'' and deleting ''labeling'' and ''packaging'' so that activities listed in the definition are consistent with activities covered by proposed part 117. As discussed in section IX.C.2 of this document, FDA is proposing to consistently use the terms ''manufacturing, processing, packing and holding'' to reflect the group of terms used in section 418(a) of the FD&C Act to broadly identify activities that take place in food facilities. As discussed later in this section, ''labeling'' and ''packaging'' would be included in the definition of manufacturing/processing and do not need to be repeated in the definition of ''plant.'' As discussed above in section IX.C.2 of this document, FDA also is proposing to replace the term ''facility'' with the term ''establishment.'' Proposed § 117.3 would define ''plant'' to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Current § 110.3(n) defines ''safe-moisture level'' as a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. Current § 110.3(n) also specifies that the maximum safe moisture level for a food is based on its water activity (a_w), and that an a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms. FDA is proposing to revise the definition for ''safe-moisture level'' to:

- Delete the hyphen between ''safe'' and ''moisture.'' The hyphen is not necessary.
- Remove the word ''maximum'' before ''safe moisture level.'' FDA tentatively concludes that this word is not needed, since the word ''maximum'' is implicit when referring to ''safe'' with respect to moisture level.
- Replace the phrase ''based on'' with ''related to.'' FDA tentatively concludes that the term ''related to'' is more appropriate because moisture level is not the only factor that determines water activity.
- Replace the phrase ''manufacturing, storage, and distribution'' with the phrase ''manufacturing, processing, packing, and holding.'' As discussed in section IX.C.1 of this document, we are proposing to use this group of terms to broadly identify activities that take place in food facilities.

With these proposed changes, proposed § 117.3 would define ''safe

moisture level'' to mean a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. Proposed § 117.3 would also specify that the safe moisture level for a food is related to its water activity (a_w), and that an a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Current § 110.3(o) defines ''sanitize'' to mean to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. FDA is proposing to revise the definition for ''sanitize'' to include the term ''cleaned'' before ''food-contact surfaces.'' It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. 125). Proposed § 117.3 would define ''sanitize'' to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

4. New Definitions

FDA is proposing to define the term ''affiliate'' to mean any facility that controls, is controlled by, or is under common control with another facility. The proposed definition would incorporate the definition in section 418(l)(4)(A) of the FD&C Act and would make the meaning of the term clear when used in the proposed definition of ''qualified facility.''

FDA is proposing to define ''calendar day'' to mean every day shown on the calendar.

FDA is proposing to define the term ''cross-contact'' to mean the unintentional incorporation of a food allergen into a food. We discuss cross-contact in more detail in section IX.D of this document.

FDA is proposing to define the term ''environmental pathogen'' to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. Examples of environmental pathogens include *Salmonella* spp. and *Listeria monocytogenes.* FDA requests comment on this definition and the types of organisms that should be considered environmental pathogens, including whether spores of pathogens such as *Clostridium perfringens* or *Bacillus cereus* should be considered environmental pathogens.

FDA is proposing to define the term ''facility'' to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act in accordance with the requirements of 21 CFR part 1, subpart H. The proposed definition would incorporate the definition in section 418(o)(2) of the FD&C Act.

FDA is proposing to define the term ''farm'' by reference to the definition of that term in proposed § 1.227. See section VIII of this document for detailed discussion of farms and mixed-type facilities. We are proposing to cross-reference the definition of ''farm'' rather than to define it in proposed part 117 because the definition of ''farm,'' under both current § 1.227(b)(3) and proposed § 1.227, includes the word ''facility'' with a meaning that is broader than the meaning of ''facility'' in section 418(o)(2) of the FD&C Act. Under part I, subpart H, the term ''facility'' is not limited to entities that are required to register under section 415 of the FD&C Act. We are proposing to cross-reference the definition to reduce the potential confusion that could result if we used the term ''facility'' to have two different meanings within proposed part 117.

FDA is proposing to define the term ''FDA'' to mean the Food and Drug Administration. Defining this term within the definitions applicable to part 117 would eliminate the need to define the term within each distinct section of the regulation and would provide for the substitution of ''Food and Drug Administration'' with ''FDA'' each time ''Food and Drug Administration appears in current part 110.

FDA is proposing to define the term ''food allergen'' to mean a major food allergen as defined in section 201(qq) of the FD&C Act. Section 201(qq) defines the term ''major food allergen'' to mean any of the following: Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans, or a food ingredient that contains protein derived from one of these foods, with certain exceptions. The proposed definition would be consistent with the requirement in section 418(a) of the FD&C Act that the owner, operator, or agent in charge of a facility ''identify and implement preventive controls to significantly minimize or prevent the occurrence of * * * hazards and provide assurances that [food manufactured, processed, packed, or held by the facility] is not * * * misbranded under section 403(w) [of the FD&C Act].'' Section 403(w) of the FD&C Act provides certain labeling requirements for foods that bear or contain a major food allergen, with certain exceptions.

FDA is proposing to define the term ''harvesting'' as applicable to farms and farm mixed-type facilities and meaning activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. The proposed definition would also specify that harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership; and that harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. The proposed definition would state that gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting. We are proposing to use the same definition of ''harvesting'' as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''harvesting.''

FDA is proposing to define ''hazard'' to mean any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines (Ref. 34) and our HACCP regulation for juice (§ 120.3(g)) define ''hazard'' and ''food hazard,'' respectively as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The Codex HACCP Annex defines ''hazard'' as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (Ref. 35). Our HACCP regulation for seafood (§ 123.3(f)) and the FSIS HACCP regulation for meat and poultry (9 CFR 417.1) define ''food safety hazard'' as any biological, chemical, or physical

property that may cause a food to be unsafe for human consumption. A difference between the proposed definition of ''hazard'' and the definitions established in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry is that the proposed definition would include radiological agents whereas the various definitions of ''hazard,'' ''food hazard'' and ''food safety hazard'' under these HACCP systems do not. We are proposing to include radiological agents to implement section 418(b)(1)(A) of the FD&C Act, which includes radiological hazards as an example of known or reasonably foreseeable hazards that may be associated with the facility. We describe biological, chemical, radiological, and physical hazards in sections II.D and XII.B.3 of this document.

FDA is proposing to define the term ''hazard that is reasonably likely to occur'' to mean a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls. The proposed definition is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. Our HACCP regulation for seafood describes a food safety hazard that is reasonably likely to occur as one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls (§ 123.6(a)). Our HACCP regulation for juice describes a food hazard that is reasonably likely to occur as one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed (§ 120.7(a)(2)). The FSIS HACCP regulation for meat and poultry describes a food safety hazard that is reasonably likely to occur as one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls (9 CFR 417.2(a)). In section XII.B.4 of this document, we explain how the term ''hazard that is reasonably likely to occur'' would implement section 418(b)(1) of the FD&C Act and relate this term to the NACMCF HACCP guidelines and the Codex HACCP Annex.

FDA is proposing to define the term ''holding'' to mean the storage of food. The proposed definition would also state that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks; and that, for farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. We are proposing to use the same definition of ''holding'' as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''holding.''

FDA is proposing to define the term ''manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. The proposed definition would also specify that, for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. We are proposing to use the same definition of ''manufacturing/processing'' as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''manufacturing/processing.''

FDA is proposing to define the term ''mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The proposed definition would also state that an example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. We are proposing to use the same definition as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''mixed-type facilities.''

FDA is proposing to define the term ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The proposed definition is the same as the definition in our HACCP regulation for juice (§ 120.3(i)). The NACMCF guidelines define ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification (Ref. 34). The Codex HACCP Annex defines ''monitor'' to mean the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (Ref. 35). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry were each established before the current NACMCF HACCP guidelines and do not define the term ''monitor.'' However, as discussed in section XII.E of this document, both of these regulations establish requirements that are consistent with the definition of ''monitor'' in proposed § 117.3 and in the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice.

FDA is proposing to define the term ''packaging'' to mean (when used as a verb) placing food into a container that directly contacts the food and that the consumer receives. FDA is proposing to use the same definition of ''packaging'' as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''packaging.''

FDA is proposing to define the term ''packing'' to mean placing food into a container other than packaging the food. The proposed definition would also specify that, for farms and farm mixed-type facilities, packing also includes activities traditionally performed by

farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. We are proposing to use the same definition of ''packing'' as would be established in proposed § 1.227. See section VIII.E of this document for a detailed discussion of ''packing.''

FDA is proposing to define the term ''preventive controls'' to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. The proposed definition would incorporate the definition in section 418(o)(3) of the FD&C Act.

FDA is proposing to define the term ''qualified end-user'' to mean, with respect to a food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that (1) is located (a) in the same State as the qualified facility that sold the food to such restaurant or establishment; or (b) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. The proposed definition would incorporate the definition in section 418(l)(4)(B) of the FD&C Act.

FDA is proposing to define the term ''qualified facility'' to mean (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility as to which both of the following apply:

- During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

The proposed definition would incorporate the description of ''qualified facility'' in section 418(l)(1) of the FD&C Act with editorial changes to improve clarity.

FDA is proposing to define the term ''qualified individual'' to mean a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system. FDA is proposing to define the term ''qualified individual'' to have a concise term to use in proposed provisions that would require that an activity be performed by such an individual. We are proposing to establish requirements for a qualified individual in proposed section § 117.155 (see section XII.H of this document).

FDA is proposing to define the term ''ready-to-eat food (RTE food)'' to mean any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards. Our proposed definition is consistent with the definition in the Codex Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria Monocytogenes in Foods (Ref. 52), which defines an RTE food as any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps. By referring to ''any other food, including processed food,'' our proposed definition for RTE food, in combination with our proposed definition of ''manufacturing/processing,'' would incorporate the concepts in the Codex guidelines for control of *Listeria* that RTE food includes foods that have been processed, mixed, cooked, or otherwise prepared into a form that can be eaten without processing in a manner that adequately reduces pathogens. Our proposed definition would generalize the Codex definition established for the purpose of guidelines directed to a single hazard—i.e., the environmental pathogen *L. monocytogenes*—to any biological hazard that would be addressed under section 418 of the FD&C Act. In so doing, our proposed definition would state that RTE foods are normally eaten without further ''processing that will significantly minimize biological hazards,'' rather than ''listericidal steps.'' In a draft guidance directed to the control of *L. monocytogenes* in refrigerated or frozen RTE foods (Ref. 126), we defined RTE food to mean ''a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.'' We are proposing a definition of RTE food that is more closely aligned to the definition in the Codex guidelines on the control of *Listeria* than the definition in our draft guidance regarding the control of *Listeria* to emphasize that RTE foods include foods that are already processed to some degree but have reached the point at which no further steps to significantly minimize biological hazards will be applied before it is eaten. This emphasis is needed for clarity with respect to proposed requirements that would be directed to control of environmental pathogens at a facility. As discussed in section XII.B.4.b of this document, proposed § 117.130(c)(2) would require that a hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. As discussed in section XII.G.7 of this document, under proposed § 117.135(d)(3) preventive controls must include, as appropriate and where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls that include procedures for the (A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and (B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

Our proposal to include in the proposed definition of RTE food the concept that it includes food that ''is reasonably foreseeable that the food would be eaten without further processing to significantly minimize biological hazards'' would retain the concept, in the draft guidance directed to the control of *L. monocytogenes* in

refrigerated or frozen RTE foods, that an RTE food includes food that ''reasonably appears to be suitable for consumption without cooking by the consumer.'' For example, it is well known that consumers eat raw cookie dough; an outbreak of foodborne illness caused by *E. coli* O157:H7 has been linked to consumption of raw cookie dough (Ref. 77). It also is well known that consumers use dried soup mix in RTE form as a component of a dip; multiple dried soup mix products were recalled due to the potential for contamination with *Salmonella* spp. from an ingredient (hydrolyzed vegetable protein) (Ref. 24).

FDA is proposing to define the term ''reasonably foreseeable hazard'' to mean a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. The term ''reasonably foreseeable hazard'' is not used in NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice, or meat and poultry. However, the term is used in FSMA and, as discussed in section XII.B.2.a of this document, the concept is grounded in the hazard evaluation process in HACCP systems.

FDA is proposing to define the term ''significantly minimize'' to mean to reduce to an acceptable level, including to eliminate. The specific terms ''significantly minimize'' and ''preventive control'' are not used in the NACMCF HACCP guidelines, the Codex HACCP Annex, or Federal HACCP regulations for seafood, juice, or meat and poultry. However, these terms are used in FSMA and are consistent with the definition of ''control measure'' in the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice. The NACMCF HACCP guidelines define ''control measure'' as any action or activity that can be used to prevent, eliminate or reduce a significant hazard (Ref. 34). The Codex HACCP Annex defines ''control measure'' as any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. 35). Our HACCP regulation for juice defines ''control measure'' as any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard (§ 120.3(c)). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, which were established prior to the current NACMCF HACCP guidelines, do not define ''control measure.'' However, these Federal HACCP regulations nonetheless reflect the same concept that would be established in the proposed definition of ''significantly minimize'' in the definition of ''critical control point,'' which is defined in the HACCP regulation for seafood as a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels (§ 123.3(b)) and in the FSIS HACCP regulation for meat and poultry as a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels (9 CFR 417.1).

FDA is proposing to define the term ''small business'' to mean, for the purposes of part 117, a business employing fewer than 500 persons. See section X.B.5 for additional discussion of the definition of small business.

FDA is proposing to define the term ''subsidiary'' to mean any company which is owned or controlled directly or indirectly by another company. The proposed definition would incorporate the definition in section 418(l)(4)(D) of the FD&C Act.

FDA is proposing to define the term ''validation'' to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and our HACCP regulation for juice. The NACMCF guidelines (Ref. 34) and our HACCP regulation for juice (§ 120.3(p)) define validation as that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards. The Codex HACCP Annex defines validation as obtaining evidence that the elements of the HACCP plan are effective (Ref. 35). Another Codex document (i.e., ''Guidelines for the Validation of Food Safety Control Measures'' (Codex validation guidelines)) defines validation more broadly than in the realm of HACCP systems as obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome (Ref. 127). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, do not define the term ''validation.'' We discuss our proposed requirements for validation (proposed § 117.150(a)), and their relationship to HACCP systems, in section XII.G.2.a of this document.

FDA is proposing to define the term ''verification'' to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. The proposed definition is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex and validation guidelines, and our HACCP regulation for juice. The NACMCF guidelines (Ref. 34), and our HACCP regulation for juice (§ 120.3(q)) define verification as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The Codex HACCP Annex defines verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Ref. 35). The Codex validation guidelines define verification as the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure is or has been operating as intended (Ref. 127). Our HACCP regulation for seafood, and the FSIS HACCP regulation for meat and poultry, do not define the term ''verification.''

FDA is proposing to define the term ''very small business'' to mean, for the purposes of proposed part 117, a business that has less than $250,000 in total annual sales of foods, adjusted for inflation (Option 1 of co-proposal). As one co-proposal, we are proposing to define the term ''very small business'' to mean a business that has less than $500,000 in total annual sales of foods, adjusted for inflation (Option 2). As another co-proposal, we are proposing to define the term ''very small business'' to mean a business that has less than $1,000,000 in total annual sales of foods, adjusted for inflation (Option 3). See section X.B.5 for additional discussion of the definition of very small business.

5. Food Processing Sector Study and the Definitions of ''Small Business'' and ''Very Small Business''

FDA conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 32) . The purpose of that study was to make determinations in five areas as required by section 418(l)(5)(A) of the FD&C Act and to use the results of the study in defining the terms ''small business'' and ''very small business.'' These areas include, in part, (1) distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4)

the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food. The Food Processing Sector Study provides information on the number of establishments and average sales per establishment by industry and size of operation. FDA's proposed definitions are informed by that study. The food processing sector study is available in the docket established for this proposed rule (Ref. 32). We request comment on that study. We will consider comments regarding the study, as well as comments regarding our proposed definitions ''small business'' and ''very small business,'' in any final rule based on this proposed rule.

Section 418(l)(5)(B) of the FD&C Act required consideration of harvestable acres, income, the number of employees, and the volume of product in defining the terms ''small business'' and ''very small business.'' The Food Processing Sector Study (Ref. 32) concluded that there was no consistent pattern across food categories in terms of which sizes of establishments contribute most to foodborne illness risk. ''Harvestable acres,'' ''income,'' ''the number of employees,'' and ''the volume of food harvested'' are all ways to measure the size of an operation. Income does not appear to be the most relevant measure, since facility income may be derived from multiple sources, many of which are not food-related. ''Harvestable acres'' and ''volume of food harvested'' are similar measures that appear primarily relevant to the growing and harvesting of crops, which are activities not subject to this regulation. Harvestable acres and volume of food harvested do not provide a meaningful measure with respect to the risk from food produced by a farm mixed-type facility (a food facility co-located on a farm subject to this regulation); our qualitative risk assessment of manufacturing, processing, packing and holding activities conducted in a facility co-located on a farm showed that risk was related to activity/food combinations; these foods could be harvested from large or small farms (see section VIII.G of this document for a discussion of that qualitative risk assessment). A high risk activity/food combination could be conducted on a farm with many harvestable acres or very few harvestable acres. For example, an on-farm facility producing bagged salads (which would not be considered a low-risk activity/food combination) could be one that has very few acres, or the bagged salads production could be a small component of a large vegetable growing farm. FDA has previously used both number of employees and annual sales as criteria for defining small and very small businesses, e.g., in 21 CFR 120.1(b)(1) and (b)(2). We have limited data on number of employees, income, and annual sales upon which to base our definitions of small and very small business, but no data for ''harvestable acres'' or ''the volume of food harvested.''

a. Definition of ''Small Business.'' FDA is proposing to define the term ''small business'' to mean, for the purposes of part 117, a business employing fewer than 500 persons. The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. We are proposing to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR 121 for most food manufacturers. This is also the same definition for small business as we used to define a small business in our juice HACCP regulation (§ 120.1(b)(1)). The definition of small business is relevant to two provisions in the proposed rule. It would affect which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/processing, of food by a small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections. It would also affect what the compliance date is for such facilities.

Effect on proposed § 117.5(g) and proposed § 117.5(h).

Under proposed § 117.5(g) a farm mixed-type facility that meets the definition of a small business and only conducts specific packing or holding activity/food combinations would be eligible for an exemption from subpart C. Similarly, under proposed § 117.5(h) a farm mixed-type facility that meets the definition of a small business and only conducts specific manufacturing/processing activity/food combinations would be eligible for an exemption from subpart C. Based on the Food Processing Sector Study, we estimate that approximately 97,169 facilities would be part of a small business under the proposed definition and thus satisfy the size requirement of the exemption in proposed § 117.5(g) and proposed § 117.5(h). Of those facilities, we estimate that approximately 1,661 would be co-located on farms. A subset of those facilities would qualify for the exemption from Subpart C based on their manufacturing/processing and packing and holding activities.

Other Effects.

Based on the Food Processing Sector Study we estimate that businesses employing fewer than 500 employees produce approximately 18 percent (based on sales) of all manufactured food produced in the United States. As discussed in section VII of this document, the compliance date for a small business would be 2 years after the date of publication of the final rule. Under our proposed definition, 97,169 facilities would be subject to this compliance date.

b. Definition of ''Very Small Business.'' In addition to defining ''small business,'' FDA is required to define ''very small business.'' FDA has not reached a tentative conclusion on how best to define ''very small business'' for the purposes of this rule. Consequently, we are proposing three possible definitions based on annual sales of $250,000, $500,000, or $1,000,000 and requesting comment on which of these three options to include in a final rule. All three proposed definitions are informed by the findings of the Food Processing Sector Study (Ref. 32). We request comment on whether a dollar amount of sales that is more than, or less than, the $250,000, $500,000, or $1,000,000 dollar amounts we are proposing would be appropriate. We also request comment on how a particular dollar amount of sales would be in keeping with Congressional intent—i.e., in light of the provisions in section 418(l) regarding qualified facilities, including the statutory limitations on sales to qualified end-users.

The definition of very small business is relevant to 3 provisions of the proposed rule. It would affect which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/processing, of food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections. It would also affect which facilities are automatically ''qualified'' facilities subject to the modified requirements in § 117.201 and what the compliance date is for such facilities.

i. Effect on proposed § 117.5(g) and proposed § 117.5(h). The definition of very small business affects which facilities qualify for the exemption in § 117.5(g) for on-farm packing or holding, and the exemption in § 117.5((h) for on-farm manufacturing/

processing, of food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/food combinations listed in those sections,

ii. Other Effects. The definition of very small business affects which facilities are automatically ''qualified'' facilities subject to the modified requirements in § 117.201, and the applicable compliance dates for such facilities. There are two ways a facility may be ''qualified'' and thus subject to the modified requirements in proposed § 117.201. The first, limited annual monetary value of sales, is based on fixed criteria set out in FSMA § 418(l)(1)(C). The second, as provided by § 418(l)(1)(B), is to be a very small business as defined by FDA. Therefore, we discuss the affect of the proposed definitions for very small business in relation to the existing requirements for qualified facilities in § 418(l)(1)(C).

Less than $250,000 in Total Annual Sales—Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term ''very small business,'' for the purposes of proposed part 117, would be a business that has less than $250,000 in total annual sales of foods, adjusted for inflation (Option 1 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 736 facilities would meet the size requirement for the exemptions in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $250,000 in Total Annual Sales—Effect on number of qualified facilities.

The proposed definition of $250,000 uses a dollar amount for sales that is, essentially, the same as the maximum dollar amount of sales by a qualified facility to end-users other than those that would satisfy the definition of ''qualified end-users,'' except unlike with § 418(l)(1)(C), there would be no requirement that more than half of sales must be to qualified end-users. The $250,000 definition of very small business would add approximately 34,600 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 46,100 domestic qualified facilities. These 46,100 domestic qualified facilities would have a 3 year compliance date. As a group, businesses with less than $250,000 in total annual sales of foods produce less than one-half of one percent of all food produced in the United States when measured by dollar value.

Less than $500,000 in Total Annual Sales—Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term ''very small business,'' for the purposes of proposed part 117, would be a business that has less than $500,000 in total annual sales of foods, adjusted for inflation (Option 2 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 903 facilities would meet the size requirement for the exemptions in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $500,000 in Total Annual Sales—Effect on number of qualified facilities.

Defining very small business to mean a business that has less than $500,000 in total annual sales of foods would add approximately 45,900 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 57,400 domestic qualified facilities. These 57,400 domestic qualified facilities would have a 3 year compliance date. As a group, businesses with less than $500,000 in total annual sales of foods produce less than one percent of all food produced in the United States when measured by dollar value.

Less than $1,000,000 in Total Annual Sales—Effect on proposed § 117.5(g) and proposed § 117.5(h).

One possible definition of the term ''very small business,'' for the purposes of proposed part 117, would be a business that has less than $1,000,000 in total annual sales of foods, adjusted for inflation (Option 3 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 1,227 facilities would meet the size requirement for the exemption in proposed § 117.5(g) and proposed § 117.5(h). A subset of those facilities would then qualify for the exemption from Subpart C based on their manufacturing/processing, packing or holding activities.

Less than $1,000,000 in Total Annual Sales—Effect on number of qualified facilities.

As compared to option two, defining very small business to mean a business that has less than $1,000,000 in total annual sales of foods would add approximately 63,500 domestic facilities to the number of qualified facilities beyond the approximately 11,500 domestic facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 75,000 domestic qualified facilities. These 75,000 domestic qualified facilities would have 3 year compliance date. As a group, businesses with less than $1,000,000 in total annual sales of foods produce less than two percent of all food produced in the United States when measured by dollar value.

C. Proposed § 117.5—Exemptions

For a summary list of the exemptions in proposed § 117.5, see the table in the Executive Summary of this document.

1. Proposed § 117.5(a)—Exemption Applicable to a Qualified Facility

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' We describe what a qualified facility is in section XIII.A of this document, where we propose the modified requirements for such a facility (proposed § 117.201). We also define the term ''qualified facility'' in proposed § 117.3 (see the discussion of definitions in section X.B.4 of this document). Section 418(l)(2)(A) of the FD&C Act provides that a qualified facility ''shall not be subject to the requirements under [sections 418(a) through (i) and (n) of the FD&C Act];'' as a practical matter with respect to the provisions of this proposed rule, section 418(l)(2)(A) of the FD&C Act provides that a qualified facility would be exempt from the proposed requirements of subpart C. Importantly, section 418(l)(3) of the FD&C Act provides that the Secretary of HHS may withdraw the exemption provided in section 418(l)(2)(A) under certain circumstances. We discuss the withdrawal provisions of section 418(l)(3), and our proposed provisions to implement section 418(l)(3) (proposed subpart E), in section XIV of this document.

We tentatively conclude that we should include the exemption provided in section 418(l)(2)(A) of the FD&C Act in the proposed rule to establish by regulation the reach of the provision. Proposed § 117.5(a) would provide that subpart C would not apply to a qualified

facility, except as provided by subpart E (i.e., except as provided by the proposed provisions for withdrawal), and that qualified facilities are subject to the modified requirements in § 117.201.

2. Proposed § 117.5(b) and (c)—Exemptions Applicable to Food Subject to HACCP Requirements for Fish and Fishery Products or for Juice

Section 418(j)(1)(A) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility that is required to comply with, and is in compliance with, the Seafood Hazard Analysis Critical Control Points Program. Likewise, section 418(j)(1)(B) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, ''[t]he Juice Hazard Analysis Critical Control Points Program* * *.'' (We interpret ''Juice Hazard Analysis Critical Control Points Program'' to mean the requirements of part 120 for juice.)

The purpose of sections 418(j)(1)(A) and (B) appears clear—to exclude food covered by and in compliance with current HACCP requirements (parts 120 and 123) from section 418 of the FD&C Act. The exclusion likely reflects a determination that the similarity of the existing HACCP requirements in parts 120 and 123 to the preventive control requirements in section 418 makes application of section 418 unnecessary to foods currently subject to and in compliance with part 120 or 123. Although the purpose of the exemption appears clear, FDA considers the language of sections 418(j)(1)(A) and (B) to be ambiguous with regard to application of the exemption. The language of sections 418(j)(1)(A) and (B) premise exemption from section 418 on an owner, operator, or agent in charge of a facility being required to comply with, and being in compliance with, part 120 or 123 ''with respect to such facility[.]'' However, parts 120 and 123 do not apply to ''facilities,'' establishments, or plants. Rather, they apply to the specified foods (juice and fish and fishery products, respectively) and to persons defined as ''processors'' who conduct certain activities involving those foods. See, e.g., § 120.1 (''The requirements of this part shall apply to any juice * * *''), § 120.3(k) (definition of ''Processor''), § 123.3(l) (definition of ''Processor''), and § 123.6(b) (''The purpose of this part is to set forth requirements specific to the processing of fish and fishery products''). Thus, it is unclear for purposes of sections 418(j)(1)(A) and (B) under what circumstances a juice or seafood processor is required to comply with parts 120 or 123 ''with respect to [a] facility,'' especially when such a person also conducts activities involving other foods not subject to parts 120 or 123 at the same facility. Because of this ambiguity, FDA considered three possible interpretations.

First, we could interpret sections 418(j)(1)(A) and (B) to exempt all food manufactured, processed, packed, or held by a facility from section 418 of the FD&C Act if the owner, operator, or agent in charge of the facility is required to comply with and is in compliance with part 123 or 120 with respect to any activities in the facility. Under this interpretation, food manufactured, processed, packed, or held by a facility that is not subject to part 120 or 123 would be excluded from section 418 if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 or 123 for any food manufactured, processed, packed, or held by the facility. For example, if a facility processes juice products and the owner, operator, or agent in charge is in compliance with the juice HACCP regulation (part 120), all food manufactured, processed, packed, or held by the facility—both the juice subject to part 120 and food not subject to part 120 (e.g., dairy products)—would be exempt from section 418. The exclusion for juice appears consistent with the purpose of section 418(j)(1)(B) because the juice is already subject to the HACCP requirements in part 120. The resulting exclusion for dairy products, however, does not serve the purpose of the exclusion because the dairy products are not subject to the HACCP requirements in parts 120 or 123. Further, the exclusion of food not subject to part 120 or 123 (e.g., dairy products) would create a gap in the coverage of preventive controls, and therefore not be protective of public health.

For example, there could be hazards reasonably likely to occur with regard to the dairy products, including environmental pathogens such as *L. monocytogenes,* but such hazards would not trigger any preventive control requirements because the facility would be excluded from section 418 of the FD&C Act. Finally, there is no apparent reason to regulate the same type of food not subject to part 120 or 123 (e.g., dairy products) differently depending on whether the food is manufactured, processed, packed, or held by a facility that manufactures, processes, packs, or holds other food that is subject to part 120 or 123. Therefore, we tentatively conclude that this interpretation results in an exclusion that is too broad.

Second, we could interpret sections 418(j)(1)(A) and (B) to exempt an entire facility from section 418 only if the owner, operator, or agent in charge of the facility is subject to and in compliance with part 120 or 123 with regard to all food manufactured, processed, packed, or held by the facility. Under this interpretation, juice and seafood in a facility would, in addition to being subject to part 120 or 123, be subject to the requirements in section 418 if the facility manufactures, processes, packs, or holds any food not subject to part 120 or 123. For example, juice processing activities subject to part 120 at a facility that processes juice and dairy products would be subject to section 418 because the facility manufacturers, processes, packs, or holds food not subject to part 120 or 123. The resulting application of section 418 to the dairy products in the example is a logical outcome—the dairy products are not subject to any other preventive control-type requirements. Further, the coverage gap created by the first possible interpretation is avoided. The application of section 418 to the juice in the example, however, is problematic. The juice is subject to part 120, thus application of section 418 to the juice would result in a circumstance that the exclusion in sections 418(j)(1)(A) and (B) was likely intended to avoid—subjecting food covered by current HACCP requirements to additional preventive control requirements in section 418. Therefore, we tentatively conclude that this interpretation results in an exclusion that is too narrow.

Finally, we considered a third interpretation. We could interpret sections 418(j)(1)(A) and (B) of the FD&C Act to exempt those activities of a facility that are subject to part 120 or 123, and only those activities, regardless of whether the facility manufactures, processes, packs, or holds other food. This interpretation would fulfill the apparent goal of the exemption— to exclude food covered by and in compliance with current HACCP requirements (parts 120 and 123) from section 418. Further, this interpretation is neither too broad (because it does not exclude food that is not subject to part 120 or 123) nor is it too narrow (because it does not result in overlapping requirements when food not subject to part 120 or 123 is processed in the same facility as food that is subject to part 120 or 123). This is the interpretation that seems most reasonable and that we propose to adopt in this proposed rule. We request comment on our

interpretation of sections 418(j)(1)(A) and (B).

We tentatively conclude that we should include the exemptions provided in sections 418(j)(1)(A) and (B) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as we have interpreted it. Proposed § 117.5(b) would provide that Subpart C would not apply with respect to activities that are subject to part 123 (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 with respect to such activities. Likewise, proposed § 117.5(c) would provide that Subpart C would not apply with respect to activities that are subject to part 120 (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 with respect to such activities. Proposed § 117.5(b) and (c) would make clear that the exemptions provided by sections 418(j)(1)(A) and (B) of the FD&C Act would apply to particular activities at a facility rather than to the facility as a whole. For example, a facility producing juice and dairy beverages would be exempt only with respect to juices subject to, and in compliance, with part 120. Such a facility would be subject to subpart C with respect to its dairy beverages, unless it qualified for another exemption.

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 123 or part 120.

3. Proposed § 117.5(d)—Exemption Applicable to Food Subject to Part 113—Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers

Section 418(j)(1)(C) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, ''[t]he Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the [FDA] (or any successor standards).'' (We interpret ''Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards'' to mean the requirements of part 113.) Importantly, section 418(j)(2) of the FD&C Act limits the express exemption associated with part 113 to microbiological hazards that are regulated under part 113 (or any successor regulations). FDA considers the language of section 418(j)(1)(C) of the FD&C Act to be ambiguous with regard to application of the exemption. As discussed with regard to sections 418(j)(1)(A) and (B) above, the language of section 418(j)(1)(C) premises exemption from section 418 of the FD&C Act on an owner, operator, or agent in charge of a facility being required to comply with, and being in compliance with, part 113 ''with respect to such facility[.]'' However, part 113 does not apply to ''facilities,'' establishments, or plants. Rather, it applies to the specified foods (low-acid canned foods) and to persons defined as ''commercial processors'' who conduct certain activities involving those foods. See, e.g., § 113.3(d) (definition of ''Commercial processor''), and section 404 of the FD&C Act (21 U.S.C. 344), which provides FDA with legal authority to issue part 113 (''[The Secretary] shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food [presenting specific risks defined in the section] in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food * * *''). Thus, it is unclear for purposes of section 418(j)(1)(C) under what circumstances a low-acid canned food processor is required to comply with part 113 ''with respect to [a] facility,'' especially when such a person also conducts activities involving other foods not subject to part 113 at the same facility.

We considered the same three interpretations of section 418(j)(1)(C) of the FD&C Act as we considered for sections 418(j)(1)(A) and (B) of the FD&C Act for the purpose of proposed § 117.5(b) and (c). We tentatively conclude that we should interpret section 418(j)(1)(C) in the same manner as we interpreted sections 418(j)(1)(A) and (B)—i.e., to exempt those activities of a facility that are subject to part 113, and only those activities. Such an interpretation would fulfill the apparent goal of the exemption without being too narrow or too broad. We also tentatively conclude that we should include the exemption provided in section 418(j)(1)(C) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as we have interpreted it. Proposed § 117.5(d)(1) would provide that Subpart C would not apply with respect to activities that are subject to part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 with respect to such activities. For example, a facility producing both low-acid foods packaged in hermetically sealed containers and acidified foods subject to part 114 would be exempt only with respect to low-acid foods subject to, and in compliance with, part 113. Consistent with section 418(j)(2) of the FD&C Act, proposed § 117.5(d)(2) would establish that the exemption in proposed § 117.5(d)(1) would be applicable only with respect to the microbiological hazards that are regulated under part 113. A facility that is required to comply with, and is in compliance with, part 113 would be subject to the requirements in proposed subpart C for hazards such as chemical hazards (e.g., pesticide residues), physical hazards (e.g., metal fragments that could be introduced from equipment) and radiological hazards (e.g., high concentrations of radium-226, radium-228 or uranium in well water used in product). A facility that is required to comply with, and is in compliance with, part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under part 113. For example, the heat-stable toxin produced by the *Staphylococcus aureus* is a biological hazard that would not be inactivated or destroyed by the processing required under part 113 (Ref. 128) (Ref. 129).

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 113.

4. Proposed § 117.5(e)—Exemption Applicable to a Facility That Manufactures, Processes, Packs, or Holds a Dietary Supplement

Section 103(g) of FSMA provides that ''[n]othing in the amendments made by [section 103 of FSMA] shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the [FD&C Act] (21 U.S.C. 342(g)(2), 379aa–1).'' Section 402(g)(2) of the FD&C Act authorizes FDA to issue regulations to require good manufacturing practices for dietary supplements. FDA has issued such a regulation at part 111 (21 CFR 111) (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements). Section 761 of the FD&C Act requires serious adverse event reporting for dietary supplements. FDA has issued guidance implementing section 761 (Ref. 130).

We interpret section 103(g) of FSMA in a manner analogous to our

interpretation of sections 418(j) and (k) of the FD&C Act—i.e., as an exemption from the requirements for hazard analysis and preventive controls that we are proposing to establish in subpart C of proposed part 117. We interpret the reference in section 103(g) of FSMA to ''compliance with section 402(g)(2)'' to mean compliance with part 111 (i.e., the regulation authorized by section 402(g)(2) of the FD&C Act). We tentatively conclude that Congressional intent regarding the reach of section 103(g) of FSMA is unambiguous in that section 103(g) of FSMA directly limits the provision ''with regard to the manufacturing, processing, packing, or holding of a dietary supplement * * *.'' We also tentatively conclude that we should include a provision implementing section 103(g) of FSMA in the proposed rule to establish by regulation the reach of the provision. Proposed § 117.5(e) would provide that Subpart C would not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of Part 111 (Current good manufacturing practice in manufacturing, packing, labeling, or holding operations for dietary supplements) and section 761 of the FD&C Act (Serious Adverse Event Reporting for Dietary Supplements).

We request comment on the criteria that should be used to determine whether a facility is in compliance with part 111 and with section 761 of the FD&C Act.

5. Proposed § 117.5(f)—Exemptions Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act

Section 418(k) of the FD&C Act provides that section 418 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 419 [of the FD&C Act]''. Section 419, ''Standards for Produce Safety,'' requires FDA to establish by regulation ''science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death.'' Section 419(h) of the FD&C Act provides that section 419 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 418 [of the FD&C Act].'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to implement section 419. That proposed rule would apply section 419 to (1) ''farms'' (as would be defined in proposed §§ 1.227 and 1.328) that are not required to register under section 415 of the FD&C Act; and to (2) farms that conduct an activity (or activities) that triggers the section 415 registration requirement (''farm mixed-type facilities''), but only with respect to their activities that are within the farm definition and therefore do not trigger the registration requirement. See section VIII.E of this document for a discussion of our proposed revisions and additions to the definitions in current §§ 1.227(b) and 1.328.

Establishments that are exempt from registration under section 415 of the FD&C Act as ''farms'' would not be subject to section 418 of the FD&C Act when conducting activities within the farm definition. Farm mixed-type facilities would be subject to section 418 of the FD&C Act when conducting those activities that trigger the section 415 registration requirement. We tentatively conclude that Congressional intent regarding the reach of section 418(k) of the FD&C Act is unambiguous in that section 418(k) directly limits the exemption to activities of the facility that are subject to section 419 of the FD&C Act. We also tentatively conclude that we should include a provision implementing section 418(k) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption. Proposed § 117.5(f) would provide that Subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).

As discussed immediately below in section X.C.6 of this document, proposed § 117.5(g) and (h) would provide for an exemption from the requirements of proposed subpart C for certain on-farm, low-risk manufacturing, processing, packing or holding activities by a small or very small business.

6. Proposed § 117.5(g) and (h)—Exemption Applicable to Certain On-farm Manufacturing, Processing, Packing or Holding Food by a Small or Very Small Business

a. Requirements of section 103 of FSMA. As discussed in section VIII.A.1 of this document, section 103(c)(1)(A) of FSMA requires that the Secretary publish a proposed rule to promulgate regulations with respect to ''(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the [FD&C Act]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of section 415.'' Section 103(c)(1)(B) of FSMA directs that the rulemaking ''shall enhance the implementation of such section 415 [of the FD&C Act] and clarify the activities that are included as part of the definition of the term ''facility'' under such section 415.'' In section VIII of this document, we discuss clarifications of certain on-farm activities and whether they trigger the section 415 registration requirement in order to enhance the implementation of section 415 by clarifying the treatment of various activities for purposes of section 415, including activities conducted on farms.

As discussed in section VIII.A.2 of this document, section 103(c)(1)(C) of FSMA requires that the Secretary conduct a science-based risk analysis of ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.'' As discussed in section VIII.G of this document, consistent with the requirements of section 103(c)(1)(C) of FSMA we have conducted a qualitative risk assessment related to activity/food combinations for the purpose of determining which activity/food combinations would be considered low risk.

Section 103(c)(1)(D)(i) of FSMA requires that, in promulgating the regulations under Section 103(c)(1)(A), ''the Secretary shall consider the results of the science-based risk analysis conducted under [Section 103(c)(1)(C) of FSMA], and shall exempt certain facilities from the requirements in section 418 of the [FD&C Act] * * *, including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of [the FD&C Act] * * * or modify the requirements in [sections 418 or 421 of the FD&C Act], as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' Section 103(c)(1)(D)(ii) of FSMA provides that ''[t]he exemptions or modifications under [section 103(c)(1)(D)(i) of FSMA] shall not include an exemption from the requirement to register under section 415 of the [FD&C Act] * * * if applicable, and shall apply only to

small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the [FD&C Act].''

b. FDA's interpretation of section 103(c)(1)(D)(i) of FSMA. FDA considers the language of section 103(c)(1)(D)(i) of FSMA to be unambiguous with regard to the reach of the exemption. The language of section 103(c)(1)(D)(i) includes the requirement ''if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' FDA tentatively concludes that this language is unambiguous and means that Congress intended us to exempt a facility from, or modify the requirements of, section 418 of the FD&C Act under this authority if the facility only conducts a limited set of low-risk activity/food combinations that would otherwise be subject to section 418, that is, to the extent the facility is subject to section 418, it ''is engaged only in'' the identified activities involving the identified foods. This interpretation seems both protective of public health and consistent with the preventive purpose of section 418 of the FD&C Act. This interpretation would mean that a facility would be required to conduct a hazard analysis and establish and implement risk-based preventive controls for all activities conducted on all foods (including low-risk activity/food combinations) if a facility conducts a single activity subject to section 418 of the FD&C Act that is not a low-risk activity/food combination, unless the facility qualifies for another exemption from subpart C.

c. Proposed § 117.5(g)—Exemptions for on-farm low-risk packing or holding activity/food combinations. Proposed § 117.5(g) would provide that subpart C would not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership—i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Hard candy, fudge, taffy, and toffee;

(2) Cocoa beans and coffee beans (raw and roasted);

(3) Cocoa products.

(4) Grains and grain products;

(5) Honey (raw and pasteurized);

(6) Intact fruits and vegetables (for purposes of proposed §§ 117.5(g) and (h) only, ''intact fruits and vegetables'' refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts);

(7) Jams, jellies and preserves;

(8) Maple sap for syrup and maple syrup;

(9) Peanuts and tree nuts;

(10) Sugar beets, sugarcane, and sugar; and

(11) Soft drinks and carbonated water.

The low-risk on farm packing and holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VIII.G and VIII.H of this document. For purposes of proposed § 117.5(g) and (h) only, ''intact fruits and vegetables'' refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts. Cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts can be considered part of ''fruits and vegetables'' as a general matter, but FDA has addressed those foods separately for the purpose of the analysis required by section 103(c)(1)(C) of FSMA and the proposed § 117.5(g) and (h) exemptions in order to accurately reflect differences in activity/food combinations likely to be performed on farm mixed-type facilities on those foods as compared to other fruits and vegetables, as well as differences in risk across those activity/food combinations.

d. Proposed § 117.5(h)—Exemptions for on-farm low-risk manufacturing/processing activity/food combinations. Proposed § 117.5(h) would provide that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts are the following:

(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Boiling/evaporation of maple sap to make maple syrup;

(iii) Chopping peanuts and tree nuts;

(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts or tree nuts (e.g., adding seasonings);

(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);

(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);

(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);

(viii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(ix) Making sugar from sugar beets and sugarcane; and

(x) Salting raw peanuts and raw tree nuts;

(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Chopping peanuts and tree nuts;

(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples), and peanuts and tree nuts (e.g., adding seasonings);

(iv) Cooling intact fruits and vegetables using cold air;

(v) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;

(vi) Extracting oils from grains (e.g., corn, soybeans, oilseeds);

(vii) Fermenting cocoa beans and coffee beans;

(viii) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate) coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey,

jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

(x) Making hard candy, fudge, taffy, and toffee;

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making honey;

(xiii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(xiv) Making maple syrup;

(xv) Making soft drinks and carbonated water;

(xvi) Making sugar from sugar beets and sugarcane;

(xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;

(xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; and maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xix) Salting peanuts and tree nuts;

(xx) Shelling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;

(xxi) Sifting grains and grain products;

(xxii) Sorting, culling and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies, and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xxiii) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);

(xxiv) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

The low-risk on-farm manufacturing/processing activity/food combinations reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VIII.G and VIII.H of this document.

7. Proposed § 117.5(i)— Exemptions Related to Alcoholic Beverages

a. Requirements of FSMA. Section 116(a) of FSMA (21 U.S.C 2206(a)) provides that, except as provided by certain listed sections in FSMA, nothing in FSMA, or the amendments made by FSMA, ''shall be construed to apply to a facility that—(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and (2) under section 415 of the [FD&C Act] is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.''

Section 116(b) of FSMA (21 U.S.C. 2206(b)) provides that section 116(a) of FSMA ''shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that [section 116(a) of FSMA] shall apply to a facility described in [section 116(a) of FSMA] that receives and distributes non-alcohol food, provided such food is received and distributed—(1) in a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.''

Section 116(c) of FSMA (21 U.S.C. 2206(c)) provides that, ''[e]xcept as provided in [sections 116(a) and (b) of FSMA], [section 116] shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of [FSMA] (including the amendments made by [FSMA]).''

b. FDA's interpretation of Section 116(a)(1) of FSMA. FDA is aware that some facilities that manufacture, process, pack, or hold alcoholic beverages are required to obtain what is technically called a ''permit'' from the Secretary of the Treasury (''Treasury'') and some are required to ''register'' (such as ''dealers'' under 26 U.S.C. 5124) with Treasury. Others must adhere to functionally similar requirements by submitting a notice or application and obtaining approval from Treasury prior to commencing business. As examples, distilled spirits plants require a Federal Alcohol Administration Act (FAA Act) basic permit (27 U.S.C. 203–204) and must register under the Internal Revenue Code of 1986 (IRC) (26 U.S.C. 5171–72); wineries must obtain an FAA Act basic permit to produce or blend wine and as a bonded wine cellar must obtain approval of an application under the IRC (26 U.S.C. 5351 and 5356); and breweries must file a brewer's notice under the IRC and must obtain approval of that notice from Treasury (26 U.S.C. 5401). Because Treasury informs FDA that these are functionally similar requirements, and because FDA has not identified a public health basis or an indication that Congress intended for these various facilities to be treated differently for the purposes of section 116 of FSMA, FDA tentatively concludes that the phrase ''obtain a permit or register'' is ambiguous and should be interpreted broadly, to include not only facilities that must obtain what is technically named a ''permit'' or must ''register'' with Treasury, but also those facilities that must adhere to functionally similar requirements as a condition of doing business in the United States, namely, by submitting a notice or application to Treasury and obtaining Treasury approval of that notice or application. Proposed § 117.5(i)(1)(i) would provide that obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States under the relevant statutes would be treated the same as obtaining a permit or registering with Treasury under those statutes for the purposes of section 418 of the FD&C Act.

FDA understands that all of the facilities described in FSMA section 116(a)(1) are located in the United States (including Puerto Rico under the FAA Act). In isolation, therefore, section 116(a)(1) of FSMA appears to operate to exempt only certain domestic facilities from the requirements of section 418 of the FD&C Act. Under this interpretation, while domestic facilities would be exempt from section 418 of the FD&C Act if they met all of the required criteria, foreign facilities would not be exempt because they do not satisfy section 116(a)(1) of FSMA.

This raises the question of whether such a construction of section 116(a)(1) of FSMA would be consistent with the risk-based public health principles underlying section 418 of the FD&C Act and FSMA generally; and raises concerns related to U.S. trade obligations, for example, those found in the World Trade Organization Agreements. See, e.g., The General Agreement on Tariffs and Trade 1994,

(GATT 1994) Art. III(4) (''The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale* * *.''); Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS Agreement), Art. 2(3) (''Member shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members.''). Importantly, section 404 of FSMA provides that ''Nothing in this Act * * * shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.''

As a result, FDA considers the language of section 116 of FSMA, read together with the language of section 404 of FSMA, to be ambiguous with regard to foreign facilities that manufacture, process, pack, or hold alcoholic beverages. There are multiple possible interpretations of this provision. For example, section 116 of FSMA could be read to exempt only domestic facilities from the requirements of section 418 of the FD&C Act, or section 404 of FSMA could be read to make the section 116(a)(1) exemption inapplicable for all facilities for the purposes of section 418 of the FD&C Act. In considering sections 116 and 404 together, FDA tentatively concludes that it is reasonable to construe section 116(a)(1) to refer not only to domestic firms, but also to foreign firms in order to be consistent with the risk-based public health principles underlying section 418 of the FD&C Act and FSMA generally, and to avoid any inconsistency with treaties or international agreements to which the United States is a party. Accordingly, proposed § 117.5(i)(1)(i) would apply the exemption not only to domestic facilities that are required to secure a permit, registration, or approval from Treasury under the relevant statutes, but also to foreign facilities of a type that would require such a permit, registration, or approval if they were domestic facilities.

c. FDA's interpretation of Section 116(b) of FSMA. FDA also considers the language of section 116 of FSMA to be ambiguous with regard to the reach of the exemption for facilities that manufacture, process, pack, or hold alcoholic beverages and also receive, manufacture, process, pack, hold, or distribute non-alcohol food (for clarity FDA is using the term ''food other than alcoholic beverages'' rather than ''non-alcohol food'' in the codified and discussion that follows). Section 116(b) of FSMA provides that section 116(a) ''shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food,'' except when the non-alcohol food is ''received and distributed—(1) in a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.''

In order to interpret the application of section 116 to food other than alcoholic beverages, FDA must interpret the meaning of the phrase ''received and distributed * * * in a prepackaged form that prevents any direct human contact with such food'' in section 116(b) of FSMA. FDA tentatively concludes that this phrase refers to food that is completely enclosed in packaging during the entire time it is under the facility's direct control, such that direct human contact with such food is prevented. Under this interpretation, facilities that conduct activities using such packaged food without opening the packaging after receiving the food and before distributing it are receiving and distributing food in prepackaged form that prevents any direct human contact with such food. For example, a winery that assembles gift baskets containing bottles of its own wine and prepackaged boxes of crackers purchased from a supplier, without opening the boxes of crackers, would be receiving and distributing the food other than alcoholic beverages (crackers) in prepackaged form that prevents direct human contact with such food.

Considering this interpretation and the fact that alcohol-related facilities also handle food other than alcoholic beverages in other ways, one interpretation of section 116(b) could be that facilities described in 116(a) that also receive and distribute any food other than alcoholic beverages would be entirely ineligible for the exemption, and therefore wholly subject to section 418 of the FD&C Act, unless such food is received and distributed in prepackaged form and in amounts that constitute no more than 5 percent of a facility's overall sales. For example, if a brewery receives grain and distributes spent grain as animal feed, the entire brewery and all of its activities, including the manufacturing, processing, packing, and holding of beer, would be subject to section 418 of the FD&C Act under this interpretation because it receives and distributes food other than alcoholic beverages that is not in prepackaged form. However, if the same brewery simply disposed of its spent grain as waste, the brewery's manufacturing, processing, packing, and holding of beer would not be subject to section 418 of the FD&C Act. In other words, under this interpretation, whether the facility's manufacturing, processing, packing, or holding of alcohol would be subject to section 418 of the FD&C Act would depend on the facility's activities relating to food other than alcoholic beverages.

When considering the provision as a whole and in its statutory context, FDA tentatively concludes that another interpretation is more reasonable. The agency understands section 116 of FSMA, in general, to indicate that the manufacturing, processing, packing, or holding of alcoholic beverages at most alcohol-related facilities should not be subject to section 418 of the FD&C Act. FDA understands section 116(b) of FSMA to indicate that the receipt and distribution of food other than alcoholic beverages, including any manufacturing, processing, packing, or holding of such food occurring at the facility between receipt and distribution, should be subject to section 418 of the FD&C Act, unless that food is received and distributed in prepackaged form and in amounts that constitute 5 percent or less of the facility's overall sales. Thus, activities related to alcoholic beverages (including the manufacturing, processing, packing, or holding of alcoholic beverages) at facilities within the scope of 116(a) of FSMA would not be subject to section 418 of the FD&C Act. Activities related to food other than alcoholic beverages (including the receiving, manufacturing, processing, packing, holding, and distributing of such foods) would be subject to section 418 of the FD&C Act even if those activities occur at facilities that are otherwise within the scope of 116(a) (unless they qualify for another exemption or are in prepackaged form and constitute 5 percent or less of the facility's overall sales). For example, if an alcoholic beverage distillery also makes non-alcoholic beverages, under this interpretation the alcoholic beverage distilling activities would be exempt from section 418 of the FD&C Act, but the activities related to non-alcoholic beverages would be subject to section 418 (assuming the non-alcoholic beverages are not in prepackaged form and constitute less than 5 percent of the facility's overall sales) unless they

qualify for another exemption. This interpretation is also consistent with the rule of construction in section 116(c) of FSMA, which states, ''except as provided in [sections 116(a) and (b) of FSMA], [section 116 of FSMA] shall not be construed to exempt any food, other than alcoholic beverages, * * * from the requirements of this Act.''

When considering the statute as a whole, including its underlying purpose, this interpretation of section 116 also provides a more consistent, risk-based approach supported by public health principles. FDA concludes that Congress must have considered identifying hazards and implementing preventive controls for the manufacturing, processing, packing, and holding of alcoholic beverages to warrant lower priority from a public health perspective than other foods. Congress may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB). The definition of ''food'' under the FD&C Act includes ''articles used for food or drink'' and thus includes alcoholic beverages. See 21 U.S.C. 321(f). As such, alcoholic beverages are subject to the FD&C Act adulteration provisions, and implementing regulations, related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the requirements of current part 110. In addition, alcoholic beverages are regulated by TTB under the Federal Alcohol Administration Act and Chapter 51 of the Internal Revenue Code, which together establish ''a comprehensive system of controls of alcoholic beverages, including on-site inspections and procedures that require the advance approval of statements of process and of formulas showing each ingredient to be used in the product'' (Ref. 131 at II.B). FDA tentatively concludes that Congress intended to exempt certain alcohol-related facilities from section 418 of the FD&C Act because it found that, in light of the relatively low public health risk presented by the manufacturing, processing, packing, and holding of alcoholic beverages and their joint regulation by both FDA and TTB, the current regulatory scheme was sufficient to control the hazards associated with the manufacturing, processing, packing, and holding of alcoholic beverages. At the same time, FDA tentatively concludes that Congress did not intend to exempt manufacturing, processing, packing, or holding of food other than alcoholic beverages from section 418 except in the very limited circumstances set forth in section 116(b)(1) and (2) of FSMA.

At times, the manufacturing, processing, packing, or holding of alcoholic beverages is inseparable from the manufacturing, processing, packing, or holding of food other than alcoholic beverages. For example, a brewery that sells its spent grains as animal feed may be manufacturing beer and animal feed simultaneously for at least part of the brewing process. FDA tentatively concludes that section 418 of the FD&C Act does not apply to such inseparable activities. FDA tentatively concludes that section 418 applies to the food other than alcoholic beverages starting at the point at which it becomes physically separate from the alcoholic beverage because section 116(c) demonstrates Congress's intent to limit the reach of the exemption to alcoholic beverages. Thus, in the case of the brewery manufacturing animal feed, section 418 of the FD&C Act would apply to the spent grain sold as animal feed once the spent grain is physically separated from the beer, but not before that point.

Proposed § 117.5(i)(1) would provide that subpart C would not apply with respect to alcoholic beverages at facilities meeting the criteria in proposed § 117.5(i)(1)(i) and (ii). Proposed § 117.5(i)(2) would provide that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in proposed § 117.5(i)(1), provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

We tentatively conclude that we should include a provision implementing section 116 of FSMA in the proposed rule to establish by regulation the reach of the provision. We request comment on our interpretation of section 116 of FSMA.

8. Proposed § 117.5(j)—Exemption Applicable to Facilities Solely Engaged in Storage of Raw Agricultural Commodities Other than Fruits and Vegetables Intended for Further Distribution or Processing

Section 418(m) of the FD&C Act provides in relevant part that FDA may by regulation ''exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in * * * the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing''.

Proposed § 117.5(j) would exempt facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing from the requirements of subpart C. This provision would exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans), unpasteurized shell eggs, and unpasteurized milk from subpart C. This would include facilities such as grain elevators and silos, provided that such facilities do not conduct other activities subject to section 418 of the FD&C Act. Outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-fruit or vegetable RACs. In addition, as discussed in section X.C.9 of this document, facilities that are solely engaged in the storage of RACs are exempt from the current CGMP regulation, and FDA proposes to maintain this exemption from the CGMPs. FDA tentatively concludes that there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable RACs intended for further distribution or processing to the requirements of subpart C. Such facilities would remain subject to the requirements of the FD&C Act. For example, if storage is done under insanitary conditions whereby the food may become contaminated with filth or rendered injurious to health, the food would be adulterated under section 402(a)(4) of the FD&C Act.

9. Proposed § 117.5(k)—Exemption Applicable to Farms, Activities of ''Farm Mixed-type Facilities'' Within the Definition of ''Farm,'' and the Holding or Transportation of One or More Raw Agricultural Commodities

Current § 110.19(a) provides that establishments engaged solely in the harvesting, storage, or distribution of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the FD&C Act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public, are exempt from the requirements of part 110. The exemption in current § 110.19(a) is commonly referred to as the ''RAC exemption.'' Current § 110.19(b) states that we will issue special regulations if it is necessary to cover operations excluded under current § 110.19(a). In section VIII.D of

this document, we discuss the meaning of the term ''raw agricultural commodity'' (RAC).

FDA is proposing a series of changes to current § 110.19. As discussed more fully below, FDA is proposing to redesignate current § 110.19(a) as proposed § 117.5(k) and revise the newly established provision as follows:

- Delete current § 110.19(b);
- Make clear that the exemption from requirements in proposed part 117 remains limited to the current requirements (which presently are established in current part 110, subparts B, C, E, and G and would be re-established in proposed part 117, subpart B under this proposed rule); and
- Adjust and clarify what activities fall within this exemption based on experience and changes in related areas of the law since issuance of the CGMP regulation.

Proposed § 117.5(k) would provide that Subpart B does not apply to ''farms'' (as would be defined in proposed § 1.227), activities of farm mixed-type facilities (as would be defined in proposed § 1.227) that fall within the definition of ''farm,'' or the holding or transportation of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the FD&C Act.

Redesignating current § 110.19(a) as proposed § 117.5(k) would simplify the rule by listing all exemptions in a single place. Deleting current § 110.19(b) would have no substantive effect, because current § 110.19(b) establishes no binding requirement on FDA or on persons that would be subject to part 110 and is unnecessary to retain in part 110. We may issue special regulations if it is necessary to do so irrespective of whether such a possibility is provided for in part 110. Making clear that the exemption remains limited to the requirements in current part 110 is necessary because establishments that previously qualified for the RAC exemption would be subject to section 418 of the FD&C Act if they are required to register under section 415 of the FD&C Act, unless they otherwise qualify for an exemption from section 418 (in proposed § 117.5(a) through (j)).

Based on FDA's experience since issuance of the CGMP regulation and changes in related areas of the law since that time, FDA proposes to modify the existing language so that this exemption would apply to farms (as would be defined in proposed § 1.227), activities of farm mixed-type facilities that fall within the farm definition, and activities related to holding or transporting RACs.

FDA proposes to explicitly apply this exemption to ''farms'' within the meaning of that term in proposed § 1.227. In current § 110.19(a), FDA used the term ''harvesting'' to describe one type of activity that could qualify for the exemption. Current § 110.19(a) and its use of the term ''harvesting'' predated the BT Act of 2002, which exempted ''farms'' from the new authorities in sections 414 and 415 of the FD&C Act. As discussed in section VIII.C of this document, FDA developed a definition of the term ''farm'' through notice and comment rulemaking implementing those authorities. Through those rulemakings, FDA learned that the terms ''growing'' and ''harvesting'' were not enough to capture the scope of the activities traditionally done on farms, and expanded the farm definition accordingly. Further, in this rulemaking, FDA is proposing to further clarify the scope of the farm definition. FDA recognizes today that farms within the definition of ''farm'' in proposed § 1.227 grow/raise and harvest their own RACs, pack and hold their own RACs or any food they may consume themselves, and/or manufacture food for their own consumption. The term ''harvesting'' in current § 110.19(a) is narrower than the current farm definition, but FDA concludes that the RAC exemption should apply to all activities within the farm definition and not merely to harvesting because other controls (such as those in the proposed produce safety rule under section 419 of the FD&C Act, and the statutory adulteration provision for food, section 402 of the FD&C Act) are more appropriate to apply to farms and their activities than is the CGMP regulation, which was developed and established for establishments other than farms. This is consistent with how FDA has interpreted the RAC exemption with respect to farms. For example, our ''Guide to Produce Farm Investigations'' (Ref. 132) advises FDA staff that ''[f]arming operations, and subsequent operations in packing sheds and buildings, may not meet all requirements outlined in 21 CFR part 110 or recommendations in the GAP Guide (Ref. 133). However these documents serve as a useful tool in assessing whether raw agricultural products are handled under conditions that may adulterate the food.'' Farms within the proposed § 1.227 definition are also not covered by section 418 of the FD&C Act because they do not have to register under section 415 of the FD&C Act, so they are not covered by any of proposed part 117. Activities within the farm definition are addressed by the adulteration provisions of the FD&C Act and the requirements in part 118 for egg producers (as applicable), and will also be addressed (as applicable) in the proposed rule to establish produce safety standards under section 419 of the FD&C Act.

FDA also proposes to exclude activities of farm mixed-type facilities that fall within the farm definition in proposed § 1.227 from subpart B. See sections VIII.C and VIII.E of this document for a discussion of the term ''farm mixed-type facility.'' FDA tentatively concludes that the portion of a farm mixed-type facility that is within the farm definition should be treated the same for the purposes of subpart B as are the same activities on farms that only conduct activities within the farm definition. FDA also proposes to exclude activities related to holding or transporting RACs, whether or not such activities are performed on farms. The term ''holding'' would have the same meaning here as in the revisions we are proposing to current § 1.227(b)(5). Current § 110.19(a) uses the term ''storage'' to describe these activities. In proposed § 1.227, ''holding'' is defined as ''storage of food'' for establishments other than farms and farm mixed-type facilities. The term ''transportation'' would be used instead of the current term ''distribution'' to make clear that the scope of the activities exempted by that term is limited to movement of RACs in commerce by a motor vehicle or rail vehicle, and does not extend to other activities, such as packing, that might be considered to be part of the broader term ''distribution.'' Entities that would be entirely exempted by these terms in the proposed revised provision would include warehouses, silos, or other entities that only store RACs and transporters that only handle RACs. Because section 418 of the FD&C Act applies to any facility that is required to register under section 415 unless an exemption from section 418 applies, it is a separate question whether these entities would be subject to subpart C. Many of the establishments that are exempted from subpart B by this proposed provision are also likely to be exempt from subpart C or subject to modified requirements under section 418 of the FD&C Act, either because they do not have to register under section 415 (e.g., common carriers), or they qualify for an exemption or modified requirements under section 418 (e.g., modified requirements for certain warehouses under proposed § 117.7, exemption for small or very small businesses performing only on-farm low-risk activity/food combinations under

proposed § 117.5(g) and (h), exemption for facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing under proposed § 117.5(j)).

By removing the term ''distribution'' from current § 110.19(a), FDA proposes to exclude packing of RACs that does not fall within the farm definition from the revised exemption, i.e., to subject packing of RACs to the requirements of subpart B. As discussed in section II.A.1 of this document, the CGMP working group recommended that the agency consider removing the RAC exclusion entirely, and recommended that the agency request further comments on the appropriate application of CGMP controls to raw agricultural product harvesting, packing, storage and distribution (Ref. 1). These concerns were based on investigations of outbreaks linked to fresh produce that had ''identified contamination during production and harvest, initial processing and packing, distribution, and final processing as the likely source of product contamination.'' (Ref. 1). Since issuance of the CGMP working group report, FDA has continued to investigate foodborne illness outbreaks and contamination events associated with fresh produce and other RACs, and continues to be concerned about sanitation practices at establishments that pack RACs. Packing of RACs has been implicated as a likely source of contamination in multi-state foodborne illness outbreaks associated with RACs (Ref. 134) (Ref. 135) (Ref. 136).

Accordingly, FDA tentatively concludes that packing of RACs should be subject to the CGMP requirements in proposed subpart B, but that the other activities discussed above for RACs are sufficiently addressed, or will be addressed, by FDA in other ways. We seek comment on this proposal. Growing/raising and harvesting of RACs, and all activities within the farm definition, such as on-farm packing and holding of a farm's own RACs, will continue to be addressed through the statutory adulteration provisions in the FD&C Act, the requirements of part 118 for egg producers (as applicable), and the proposed rule to establish produce safety standards (as applicable) under section 419 of the FD&C Act. FDA tentatively concludes that it is appropriate to address food safety on farms in this fashion, rather than by requiring farms to comply with subpart B. Manufacturing/processing steps conducted on RACs are already subject to the current CGMP regulation and will continue to be subject to the requirements of subpart B, which applies to manufacturing/processing, including when such activities are performed on RACs. This includes manufacturing/processing steps that may occur at establishments that are commonly known as ''packinghouses,'' such as washing and treating fruits and vegetables. ''Distribution'' is a term that might include activities such as transportation and packing (including re-packing). For clarity, we now discuss those two steps separately. Transportation of non-RACs is subject to the CGMP requirements in current § 110.93, and FDA further expects to address transportation of food in more detail in rulemaking to implement the Sanitary Food Transportation Act of 2005 (Pub. L. 109–59) and section 416 of the FD&C Act (75 FR 22713, April 30, 2010). Section 416(b) of the FD&C Act requires FDA to promulgate regulations to ''require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.'' In addition, FDA is not currently aware of foodborne illness outbreaks related to RACs that were likely to have been caused by insanitary conditions during transportation conditions. This leaves only packing as a step of concern that is not being sufficiently addressed, either through application of the CGMP requirements or in another way. Therefore, FDA tentatively concludes that packing of RACs that does not fall within the farm definition should be subject to the requirements in proposed subpart B. We request comment on this conclusion and on whether there any aspects of proposed subpart B that should not apply to the packing of RACs.

Because the current exemption in § 110.19(a) is limited to ''establishments engaged solely in'' the listed activities, it does not exempt establishments that conduct any activities relating to food for human consumption other than the specifically identified activities for RACs. FDA tentatively concludes that it would be reasonable to revise the exemption so that it would exempt the specifically identified activities when performed on RACs, regardless of whether the establishment that conducts those activities also conducts other activities that do not qualify for the exemption. This is because, as in the section 418(j)(1) exemptions discussed in sections X.C.2 and X.C.3 of this document (for activities covered by parts 120, 123, and 113), it is more appropriate to subject these activities to controls other than those in proposed subpart B, and these activities should be regulated in the same way whether or not other activities subject to proposed subpart B take place at the same establishment. If activities subject to proposed subpart B do take place at the same establishment, compliance with proposed subpart B with respect to those activities should provide the necessary protection for food subject to those activities regardless of whether RACs are also stored or transported by the same establishment, or if activities inside the farm definition are conducted at the same establishment.

FDA also proposes to delete ''which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public'' from the current exemption. While this phrase captured FDA's original reasoning for providing the RAC exemption, it is confusing because many RACs are not so processed (as is often the case for fresh produce, for example) and the operative part of the exemption is that it applies to RACs, not only some RACs depending on whether they receive later manipulation.

D. Proposed § 117. 7—Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Section 418(m) of the FD&C Act provides, in relevant part, that ''[t]he Secretary may, by regulation, exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in * * * the storage of packaged foods that are not exposed to the environment.''

2. Petition Relevant to Section 418(m) of the FD&C Act

In a letter dated July 22, 2011, an industry coalition of the American Bakers Association, the American Frozen Food Institute, the Grocery Manufacturers Association, the International Bottled Water Association, the International Dairy Foods Association, the International Warehouse Logistics Association, the Peanut and Tree Nut Processors Association, and the Snack Food Association (the section 418(m) petitioners) submitted a citizen petition (Docket No. FDA–2011–P–0561). The petition requests that FDA promulgate regulations under section 418(m) of the FD&C Act ''to exempt from compliance

or modify the requirements for compliance under section 418 [of the FD&C Act] for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment, by allowing such facilities to satisfy the requirements of that section through compliance with the [CGMPs] mandated for such facilities by [current] § 110.93.'' The section 418(m) petitioners assert that the food safety issues presented by facilities used only to store packaged foods that are not exposed to the environment are essentially the same, regardless of the type of food. As such, trade associations representing a variety of product sectors are signatories to the petition and are supportive of the request to exempt such facilities from the provisions of section 418 of the FD&C Act. In the remainder of this document, we refer to packaged food not exposed to the environment as ''unexposed packaged food.'' We consider ''not exposed to the environment'' and ''unexposed'' to mean that the food is in a form that prevents any direct human contact with the food.

The section 418(m) petitioners state that most of the potential hazards and preventive controls noted in section 418 of the FD&C Act are not relevant to facilities solely engaged in the storage of unexposed packaged foods and that the foods handled in these facilities would have already been subjected to hazard analyses and preventive controls (including CGMPs) throughout the process of their manufacture and packaging for delivery to retailers and end-users. They further state that most of the preventive control activities carried out in food production settings (such as sanitation of food-contact surfaces and utensils) offer no benefit for a facility storing unexposed packaged foods and that controls such as supplier verification and recall plans would be addressed by the manufacturing facility from which the foods originated.

The section 418(m) petitioners state that the ''few hazards'' that may arise in facilities solely engaged in the storage of unexposed packaged foods, ''including those relating to environmental, climate, and pest controls, are already addressed under FDA's existing CGMPs governing warehousing and distribution [in current § 110.93].'' They state that storage facilities themselves pose ''a very limited, if any, food-safety risk'' and that they are not aware of any significant foodborne illness outbreaks attributable to storage at such facilities.

The section 418(m) petitioners note that many packaged food warehouses contain a variety of foods that can come from many different manufacturing facilities or even different companies. According to the petitioners, warehouse operators work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts.

The section 418(m) petitioners assert that the warehouse operators themselves do not have access to product formulations and other relevant information that would be necessary for them to conduct a hazard analysis, develop preventive controls, and monitor them. They state that the food manufacturer, on the other hand, does understand the products it produces and factors in the storage and distribution parameters and considerations into the hazard analysis and appropriately instructs the warehouses to ensure unexposed packaged foods are being properly stored. The section 418(m) petitioners thus assert that responsibility for hazard analysis and risk-based preventive controls under section 418 of the FD&C Act is properly and best shouldered by the food manufacturer.

The section 418(m) petitioners propose that FDA use the following language as part of its regulations implementing section 418 of the FD&C Act: ''A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 of the Federal Food, Drug, and Cosmetic Act if the facility complies with the requirements set forth at 21 CFR 110.93.''

FDA notes that petitioners also make arguments for their position relevant to ''hazards that may be intentionally introduced, including by acts of terrorism,'' as described in § 418(b)(2). As discussed in sections II.B.2.f and XII.B.1, those hazards will be addressed in a future rulemaking so FDA is not addressing that aspect of the petition in this proposal.

3. FDA's Tentative Response to the Petition

We tentatively agree in part, and disagree in part, with the section 418(m) petitioners. As discussed more fully below, we agree it is appropriate for facilities solely engaged in the storage of unexposed packaged food to be exempt from the requirements that would be established in proposed subpart C, provided that the food does not require time/temperature control for safety. For unexposed packaged food that requires time/temperature control for safety, we disagree that such an exemption is warranted, but tentatively conclude that unexposed packaged food that requires time/temperature control for safety could be subject to modified requirements rather than to the full requirements that would be established in proposed subpart C.

We disagree that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls. The principal hazard that would be identified in any hazard analysis for unexposed packaged food is the potential for the growth of, or toxin formation by, microorganisms of public health significance when an unexposed refrigerated packaged food requires time/temperature control for safety. Information about this hazard and appropriate preventive controls for this hazard is widely available (Ref. 137) (Ref. 138) (Ref. 139) (Ref. 140). For example, the 2009 Edition of FDA's Food Code defines ''Potentially Hazardous Food (Time/Temperature Control for Safety Food)'' as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation (Ref. 137). Earlier editions (e.g., the 2001 Food Code) included a similar definition for ''potentially hazardous food''; since 2005, the definition jointly refers to ''potentially hazardous food'' and ''time/temperature control for safety food'' (commonly referred to as TCS food) to emphasize the importance of temperature control in keeping food safe. Although we disagree that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls, we agree that it is not necessary for each facility solely engaged in the storage of unexposed packaged food to conduct its own hazard analysis to identify this hazard for unexposed refrigerated packaged food as reasonably likely to occur and for each such facility to determine that time/temperature control is the appropriate preventive control.

We also disagree that current § 110.93 alone is adequate for addressing environmental problems such as a flood in the facility and pest control problems, even though the food in question is not exposed to the environment and pest control problems with the container would likely be visible to the warehouse operator. However, we tentatively conclude that proposed § 117.93, along with other applicable provisions of proposed part

117, subpart B, such as pest control in proposed § 117.35, do adequately address most safety-related issues that may arise in facilities solely engaged in the storage of unexposed packaged food. We disagree that current § 110.93 or other provisions in proposed part 117, subpart B justifies the exemption from all preventive control requirements sought by the petitioners in the specific case of unexposed refrigerated packaged food that requires time/temperature control for safety (hereinafter unexposed refrigerated packaged TCS food). As discussed more fully in section XIII.B of this document, such food requires the implementation of an appropriate preventive control (temperature), monitoring that control, taking corrective actions when there is a problem with that control, verifying that the control is consistently implemented, and establishing and maintaining records documenting the monitoring, corrective actions, and verification. FDA tentatively concludes that it is appropriate for our response to the petition to distinguish between packaged food that requires such time/temperature control and packaged food that does not.

We also disagree that an exemption provided under section 418(m) of the FD&C Act should be established in a manner that has the potential to be interpreted more broadly than section 418(m) provides. The section 418(m) petitioners request that we establish a provision that ''A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 [of the FD&C Act]'', whereas section 418(m) provides discretion for an exemption ''with respect to facilities that are solely engaged in * * * the storage of packaged foods that are not exposed to the environment.'' Under proposed § 117.3, ''holding'' would mean storage of food and holding facilities would include, relevant to unexposed packaged food, warehouses and cold storage facilities. To the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged food is merely ''storing'' or ''holding'' the food, an exemption established using the language provided by section 418(m) would apply to that facility. However, to the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged food is not merely ''storing'' or ''holding'' the food, an exemption established using the language provided by section 418(m) would not apply to that facility.

In response to the petition, FDA is proposing to establish an exemption from subpart C for facilities solely engaged in the storage of unexposed packaged food (proposed § 117.7). FDA also is proposing to establish modified requirements at such facilities to require that the owner, operator, or agent in charge of such a facility comply with modified requirements for any unexposed refrigerated packaged TCS food (proposed § 117.206). See the discussion of proposed § 117.7 in the next section of this document and the discussion of proposed § 117.206 in section XIII.B of this document.

4. Proposed § 117.7—Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Proposed § 117.7(a) would provide that subpart C does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment. Proposed § 117.7(b) would establish that unexposed packaged food at such facilities is subject to modified requirements that would be established in proposed § 117.206. As discussed more fully in section XIII.B of this document, the modified requirements would mandate that such a facility establish and implement appropriate temperature controls, monitor the temperature controls, take corrective actions, verify that the temperature controls are consistently implemented, and establish and maintain records documenting the monitoring, corrective actions, and verification activities for unexposed refrigerated packaged TCS food. These modified requirements would be a subset of the proposed requirements that would be established in subpart C.

There are limited routes of contamination for unexposed packaged food in a facility that solely stores unexposed packaged food (e.g., packaged food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or if human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed part 117, subpart B (e.g., proposed §§ 117.20, 117.35, 117.37, and 117.93) would apply to the storage of unexposed packaged food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator, or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C. The exception would be for the rare circumstance in which RACs are packaged in a manner in which the RACs are not exposed to the environment. Under current § 110.19(a), an establishment solely engaged in storing RACs is exempt from CGMPs in current part 110; under proposed § 117.5(k), such an establishment would continue to be exempt from CGMPs. Such an establishment is now, and would continue to be, subject to section 402(a)(4) of the FD&C Act. An establishment that is solely engaged in the storage of packaged RACs that are not exposed to the environment may find the provisions of proposed subpart B helpful in ensuring compliance with section 402(a)(4) of the FD&C Act.

Many of the requirements that would be established in proposed subpart C would be directed to manufacturing, processing, and packing food and would not apply to the storage of unexposed packaged food that does not require time/temperature control for safety. This is the case for:

- Process controls (proposed § 117.135(d)(1));
- Food allergen controls (proposed § 117.135(d)(2));
- Sanitation controls (proposed § 117.135(d)(3));
- Monitoring of process controls, food allergen controls, and sanitation controls (proposed § 117.140);
- Corrective actions (proposed § 117.145);
- Verification (including initial validation) of process controls (proposed § 117.150); and
- A recall plan (proposed § 117.137) (recalls generally are initiated by the manufacturer, processor, or packer of the food).

FDA tentatively concludes that the outcome of a hazard analysis for storage of unexposed packaged food that does not require time/temperature control for safety is that there are no hazards reasonably likely to occur. We also tentatively conclude that there would be little public health benefit to requiring the owner, operator, or agent in charge of each facility solely engaged in the storage of such food to conduct its own hazard analysis and document that outcome in its own food safety plan. Likewise, we tentatively conclude that there would be no need for the facility to establish and implement preventive controls, with corresponding monitoring, corrective actions, or verification (including validation), because there would be no hazards reasonably likely to occur to trigger such

activities. We also tentatively conclude that there would be no need for a qualified individual to conduct activities such as preparing the food safety plan (proposed § 117.126(c)); developing the hazard analysis (proposed § 117.130(a)(3)); validating the preventive controls (proposed § 117.150(a)(1)); reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (proposed § 117.150(d)(2)); or performing reanalysis of the food safety plan (proposed § 117.150(e)(1)(iv)), because the facility would not need to conduct these activities. Thus, with the exception of the unexposed refrigerated packaged TCS food, we tentatively conclude that the food safety system that would be established in proposed subpart C is not needed to significantly minimize or prevent the occurrence of hazards that could affect unexposed packaged food at a facility solely engaged in the storage of such food.

The purpose of proposed § 117.7(b) is to make clear that although a facility solely engaged in the storage of unexposed packaged food is exempt from subpart C, such a facility is subject to modified requirements that would be established in proposed § 117.206. These requirements would apply to the storage of unexposed refrigerated packaged TCS food. We explain the basis for those proposed requirements in section XIII.B of this document.

XI. Proposed Revisions to Current Good Manufacturing Practice Requirements of Part 110 (Proposed Part 117, Subpart B)

A. Proposed Deletion of Guidance From Current Part 110

As discussed in section IX.F of this document, FDA is proposing a number of revisions to delete some guidance currently established in part 110 (e.g., provisions using ''should'' or ''compliance may be achieved by''). Table 8 identifies each of the proposed deletions and either explains the deletion or, for deletions with longer explanations, refers to the section of the preamble where the deletion is explained.

TABLE 8—PROPOSED DELETION OF GUIDANCE CURRENTLY ESTABLISHED IN PART 110

Current designation of provision that includes guidance	Guidance that FDA is proposing to delete	Explanation
§ 110.10(b)(5) (Cleanliness)	Gloves should be of an impermeable material	We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117. The use of an impermeable material may be important for handling a ready-to-eat food but may not be required for handling a food that will receive a validated heat treatment. Thus, we tentatively conclude that it would not be appropriate to require that gloves used for the handling of all foods be made of an impermeable material and that a discussion of gloves would be more appropriate in a guidance document, which could describe factors to consider in selecting and using gloves in the production of food.
§ 110.35(b)(2) (Substances used in cleaning and sanitizing).	Follow all relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of toxic cleaning compounds, sanitizing agents, and pesticide chemicals.	Although such a recommendation may be helpful and could be included in future guidance, FDA tentatively concludes that it is more properly addressed by the applicable Federal, State, and local government agencies and is outside the scope of proposed part 117.
§ 110.37(d) (Toilet facilities)	Compliance with the requirements for toilet facilities may be accomplished by four specified mechanisms.	See explanation in section XI.H.2 of this document.
§ 110.37(e) (Hand-washing facilities).	Compliance with the requirements for hand-washing facilities may be accomplished by six specified mechanisms.	See explanation in section XI.H.3 of this document.
§ 110.40(e) (Equipment and utensils).	Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.	It is now very common for freezer and cold storage compartments to be fitted with an automatic control for regulating temperature. Thus, we tentatively conclude that it is not necessary to revise current § 110.40(e) to require, rather than recommend, use of an automatic control for regulating temperature or an automatic alarm system, because the design of modern freezer and cold storage compartments has established this approach without the need for a Federal requirement.
§ 110.80(a)(2) (Processes and controls—raw materials and ingredients).	Compliance with the requirements for the safety of raw materials and ingredients may be achieved by purchasing raw materials and ingredients under a supplier's guarantee or certification.	We tentatively conclude that there are more mechanisms for achieving compliance than the single mechanism identified in current § 110.80(a)(2)—e.g., in some cases, compliance could be achieved by testing raw materials and ingredients. Rather than propose to require a subset of mechanisms to achieve compliance, FDA tentatively concludes that these recommendations would be more appropriate in a guidance document.
§ 110.80(a)(3) (Processes and controls—raw materials and ingredients).	Compliance with action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.	See explanation in section XI.J.2 of this document.

TABLE 8—PROPOSED DELETION OF GUIDANCE CURRENTLY ESTABLISHED IN PART 110—Continued

Current designation of provision that includes guidance	Guidance that FDA is proposing to delete	Explanation
§ 110.80(a)(3) (Processes and controls—raw materials and ingredients).	Compliance with the requirement for raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins to comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.	We tentatively conclude that there may be more mechanisms for achieving compliance than those mechanisms identified in current § 110.80(a)(3). Rather than propose to require a subset of mechanisms to achieve compliance, FDA tentatively concludes that these recommendations would be more appropriate in a guidance document.
§ 110.80(a)(4) (Processes and controls—raw materials and ingredients).	Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.	See explanation in section XI.J.2 of this document.
§ 110.80(a)(4) (Processes and controls—raw materials and ingredients).	The requirement for raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material to comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.	We tentatively conclude that there may be more mechanisms for achieving compliance than those mechanisms identified in current § 110.80(a)(4). Rather than propose to require a subset of mechanisms to achieve compliance, FDA tentatively concludes that these recommendations would be more appropriate in a guidance document.
§ 110.80(b)(2) (Manufacturing operations).	One way to comply with the requirement for all food manufacturing, including packaging and storage, to be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food is careful monitoring of physical factors such as time, temperature, humidity, water activity, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.	We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 and the physical factors and manufacturing operations that could be monitored to minimize the growth of microorganisms. FDA tentatively concludes that this diversity does not make it appropriate to propose establishing these specific recommendations as requirements and that these recommendations would be more appropriate in a guidance document.
§ 110.80(b)(3) (Manufacturing operations).	Compliance with the requirement for food that can support the rapid growth of undesirable microorganisms to be held in a manner that prevents the food from becoming adulterated within the meaning of the FD&C Act may be accomplished by any effective means, including maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved, maintaining frozen foods in a frozen state, maintaining hot foods at 140°F (60°C) or above, and heat treating acid or acidified foods.	We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117, as well as the temperatures that are needed for the safe holding of foods. FDA tentatively concludes that this diversity does not make it appropriate to propose to establish these specific recommendations as requirements and that these recommendations would be more appropriate in a guidance document. In addition, we note that current § 110.80(b)(3)(iv) provides for heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures. However, current § 110.80(b)(4) addresses measures, including heat treating, taken to destroy or prevent the growth of undesirable microorganisms. We tentatively conclude that proposing to revise current § 110.80(b)(3)(iv) would create a redundancy with current § 110.80(b)(4).
§ 110.80(b)(8) (Manufacturing operations).	Compliance with the requirement for effective measures to be taken to protect against the inclusion of metal or other extraneous material in food be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.	We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 and the methods that could be used to protect against the inclusion of metal or other extraneous material in food. FDA tentatively concludes that it would not be appropriate to establish such specific recommendations as requirements and that such recommendations would be more appropriate in a guidance document.

TABLE 8—PROPOSED DELETION OF GUIDANCE CURRENTLY ESTABLISHED IN PART 110—Continued

Current designation of provision that includes guidance	Guidance that FDA is proposing to delete	Explanation
§ 110.80(b)(10) (Manufacturing operations).	Protection may be provided during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming by adequate cleaning and sanitizing of all food-contact surfaces.	We considered that the cleaning and sanitizing of food-contact surfaces would already be addressed in proposed § 117.35(d), which would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food, and in proposed § 117.80(c)(1), which would require, in relevant part, that equipment and utensils be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary.
§ 110.80(b)(10) (Manufacturing operations).	Protection may be provided during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming by using time and temperature controls at and between each manufacturing step.	We considered the diversity of food that is manufactured, processed, packed or held and would be subject to the requirements of proposed part 117 and that use of time and temperature controls at and between each manufacturing step may not be required for all foods. For example, the use of time and temperature controls would not be necessary for shelf-stable foods used as ingredients in another product. FDA tentatively concludes that this recommendation would be more appropriate in a guidance document.
§ 110.80(b)(12) (Manufacturing operations).	Recommendations for how to comply with requirements for batters, breading, sauces, gravies, dressings, and other similar preparations to be treated or maintained in such a manner that they are protected against contamination.	Recommendations to comply by using ingredients free of contamination, employing adequate heat processes where applicable, and providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them, would already be addressed in proposed §§ 117.80(b)(2), 117.80(c)(2), 117.80(c)(4) and 117.80(c)(10), respectively. As discussed regarding our proposed revisions to current § 110.80(b)(10) earlier in this section, FDA tentatively concludes that establishing requirements for time and temperature controls is not appropriate in light of the diversity of food operations. The remaining recommendations regarding cooling batters to an adequate temperature and disposing of batters at appropriate intervals are better addressed in guidance. Therefore, FDA is proposing to provide flexibility to industry by retaining the performance standard in current § 110.80(b)(12) (i.e., protection against contamination) but deleting the examples of mechanisms to achieve compliance rather than proposing to establish these recommendations as requirements.
§ 110.80(b)(13) (Manufacturing operations).	Compliance with the requirement for filling, assembling, packaging, and other operations to be performed in such a way that the food is protected against contamination may be accomplished by any effective means, including (i) use of a quality control operation in which the critical control points are identified and controlled during manufacturing; (ii) adequate cleaning and sanitizing of all food-contact surfaces and food containers; (iii) using materials for food containers and food- packaging materials that are safe and suitable, as defined in § 130.3(d); (iv) providing physical protection from contamination, particularly airborne contamination; and (v) using sanitary handling procedures.	FDA is proposing to provide flexibility to industry by retaining the performance standard in current § 110.80(b)(12) (i.e., protection against contamination) but deleting the examples of mechanisms to achieve compliance. FDA tentatively concludes that such examples would be more appropriate in a guidance document.
§ 110.80(b)(14) (Manufacturing operations).	Mechanisms for compliance with the requirement for food (such as dry mixes, nuts, intermediate moisture food, and dehydrated food) that relies on the control of water activity for preventing the growth of undesirable microorganisms to be processed to and maintained at a safe moisture level.	We considered that the listed mechanisms are not the only possible mechanisms for achieving compliance. FDA tentatively concludes that it would not be appropriate to establish these recommendations as requirements and that such recommendations would be more appropriate in a guidance document.

TABLE 8—PROPOSED DELETION OF GUIDANCE CURRENTLY ESTABLISHED IN PART 110—Continued

Current designation of provision that includes guidance	Guidance that FDA is proposing to delete	Explanation
§ 110.80(b)(15) (Manufacturing operations).	Compliance with the requirement for food (such as acid and acidified food) that relies principally on the control of pH for preventing the growth of undesirable microorganisms to be monitored and maintained at a pH of 4.6 or below may be accomplished by any effective means, including employment of one or more of the following practices: (i) monitoring the pH of raw materials, food in process, and finished food and (ii) controlling the amount of acid or acidified food added to low-acid food.	We considered that the listed mechanisms are not the only possible mechanisms for achieving compliance. FDA tentatively concludes that it would not be appropriate to establish these recommendations as requirements and that such recommendations would be more appropriate in a guidance document.
§ 110.80(b)(17) (Processes and controls—manufacturing operations).	Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.	FDA tentatively concludes that this recommendation would be more appropriate in a guidance document, which could include examples of situations where there is no reasonable possibility for the contamination of the human food.
§ 110.110(e)	Information that a compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS–565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.	The organizational entity identified in current § 110.110(e) (i.e., HFS–565) no longer exists and FDA no longer has printed copies of the compilation of defect action levels. An electronic compilation of such current defect action levels is available on the internet (Ref. 141).

B. Other Potential Revisions to Current Guidance

As discussed in sections IX.F and XI.A of this document, FDA is proposing a number of revisions to delete some guidance currently established in part 110 (e.g., provisions using ''should'' or ''compliance may be achieved by''). In section XI.M of this document, FDA requests comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or retain them as useful recommended provisions of a comprehensive CGMP provision.

C. Proposed Revisions for Consistency of Terms

As discussed in section IX.C of this document, FDA is proposing revisions to use terms consistently throughout proposed part 117. Table 9 identifies and explains each of these proposed revisions. Because other revisions also may be proposed for certain sections included in Table 9 (e.g., if FDA also is proposing a revision to address cross-contact), Table 9 does not state the proposed requirement and instead refers to the section of this document containing the complete proposed requirement, including all proposed revisions

TABLE 9—PROPOSED REVISIONS FOR CONSISTENCY OF TERMS

Current designation	Proposed revision and explanation
§ 110.20(b) (Plant Construction and Design).	(1) Replace the phrase ''food-manufacturing purposes'' with the phrase ''food-production purposes (i.e., manufacturing, processing, packing, and holding) to consistently use the same group of terms in proposed part 117. (2) Replace the phrase ''plant and facilities'' with the single term ''plant'' as would be defined in proposed § 117.3. The requirement would be clear using the single term ''plant'' and, thus, the term ''facilities'' is unnecessary. In addition, under proposed § 117.3 (Definitions) the term ''facilities'' would be based on the definition in section 418(o)(2) of the FD&C Act, which is not how the term is used in current § 110.20(b). See section XI.F for the proposed requirement.
§ 110.20(b)(4) (Plant Construction and Design).	(3) Add ''food-packaging materials'' to the requirement that aisles or working spaces be provided between equipment and walls and be adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact. Contamination of food-packaging materials could lead to contamination of the food. See section XI.F for the proposed requirement.
§ 110.35(c) (Pest control)	Replace the phrase ''processing area'' with the phrase ''manufacturing, processing, packing and holding areas'' to consistently use the same group of terms in proposed part 117 and to provide for internal consistency between the requirements in current § 110.35(c) to not allow pests in ''any area of a food plant'' and to take effective measures to exclude pests from the plant. Pests do not belong in any areas where manufacturing, processing, packing or holding of food occurs. See section XI.G.3 for the proposed requirement.
§ 110.35(d)(1) (Food-contact surfaces)	Replace the term ''manufacturing'' with ''manufacturing/processing'' in light of our proposed definition of manufacturing/processing (see discussion of the definition of manufacturing/processing in section X.B of this document). See section XI.G.4 for the proposed requirement.
§ 110.35(d)(3) (Non-food-contact surfaces)	Add ''food-packaging materials'' to the recommendation that non-food-contact surfaces of equipment used in the operation of food plants be cleaned as frequently as necessary to protect against contamination of food. Contamination of food-packaging materials could lead to contamination of the food. See section XI.G.5 for the proposed provision.

TABLE 9—PROPOSED REVISIONS FOR CONSISTENCY OF TERMS—Continued

Current designation	Proposed revision and explanation
§ 110.35(d)(4) (Food-contact surfaces)	Add ''food-packaging materials'' to the requirement that single-service articles be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces. Contamination of food-packaging materials could lead to contamination of the food. See section XI.G.4 for the proposed requirement.
§ 110.37(a) (Water supply)	Add ''food-packaging materials'' to the requirement that any water that contacts food, food-contact surfaces, or food-packaging materials be safe and of adequate sanitary quality. Contamination of food-packaging materials could lead to contamination of the food. See section XI.H.1 for the proposed requirement.
§ 110.37(f) (Rubbish and offal disposal)	Add ''food-packaging materials'' to the requirement that rubbish and any offal be so conveyed, stored, and disposed of as to protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces. Contamination of food-packaging materials could lead to contamination of the food. See section XI.H.4 for the proposed requirement.
§ 110.80(b)(7) (Manufacturing operations)	(1) Replace the term ''storage'' with the term ''holding'' for consistency with use of the term ''holding'' throughout proposed part 117. (2) Add ''processing'' and ''packing'' as activities where protection is needed against contamination (and against cross-contact) because contamination and cross-contact can occur during any activities subject to proposed part 117. (3) Inserting an ''and,'' rather than an ''or,'' between the cited activities to make clear that the requirements for protection against cross-contact and contamination apply to all activities at a plant. See section XI.J.3 for the proposed requirement.
§ 110.110(c) (Defect action levels)	Change the designated persons who must ''observe good manufacturing practices'' and ''at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible'' from the currently identified persons, (i.e., manufacturers, distributors and holders of food) to manufacturers, processors, packers and holders of food for consistency with terminology used throughout proposed part 117. See section XI.L for the proposed requirement.

D. Proposed Revisions to Address Cross-Contact

As discussed in section IX.D of this document, FDA is proposing a number of revisions to address cross-contact. Some of these proposed revisions would clarify that an existing provision that requires protection against contamination also requires protection against cross-contact. Table 10 identifies and explains each of these proposed revisions addressing cross-contact. Table 10 does not state the proposed requirement and instead refers to the section of this document containing the complete proposed requirement, including all proposed revisions.

TABLE 10—PROPOSED REVISIONS REGARDING CROSS-CONTACT

Current designation	Nature of proposed change and explanation
§ 110.10(b) (Cleanliness)	Clarification. Poor hygiene may result in the transfer of food allergens from persons working in direct contact with food, food-contact surfaces, and food-packaging materials to food. See section XI.E.1 for the proposed requirement.
§ 110.10(b)(1) (Cleanliness)	Clarification. Appropriate use of outer garments protects against the transfer of food allergens from food to person to food. See section XI.E.1 for the proposed requirement.
§ 110.10(b)(9) (Cleanliness)	Clarification. Poor hygiene may result in the transfer of food allergens from persons working in direct contact with food, food-contact surfaces, and food-packaging materials to food. See section XI.E.1 for the proposed requirement.
§ 110.20(b)(2) (Plant construction and design).	Clarification. Inadequate construction and design of a plant can result in the transfer of food allergens to food. Separation of operations is a key means of preventing cross-contact. See section XI.F for the proposed requirement.
§ 110.20(b)(6) (Plant construction and design).	Clarification. Inadequate construction and design of a plant can result in the transfer of food allergens to food. Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air currents. See section XI.F for the proposed requirement.
§ 110.35(a) (General maintenance)	Clarification. Improper cleaning and sanitizing that leaves food residues on utensils or equipment may result in the transfer of food allergens from utensils or equipment to food, food-contact surfaces, or food packaging materials that come in contact with the improperly cleaned and sanitized surfaces. See section XI.G.1 for the proposed requirement.
§ 110.35(d) (Sanitation of food-contact surfaces).	Clarification. Inadequate sanitation of food-contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from food-contact surfaces to food. See section XI.G.4 for the proposed requirement.
§ 110.35(d)(2) (Sanitation of food-contact surfaces).	Clarification. Inadequate sanitation of food-contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from food-contact surfaces to food. See section XI.G.4 for the proposed requirement.
§ 110.35(d)(3) (Sanitation of non-food-contact surfaces).	Clarification. Inadequate sanitation of non-food contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from such surfaces to food-contact surfaces or food. See section XI.G.5 for the proposed requirement.
§ 110.35(d)(4) (Sanitation of food-contact surfaces).	Clarification. Failure to properly store single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) could lead to cross-contact. See section XI.G.4 for the proposed requirement.

TABLE 10—PROPOSED REVISIONS REGARDING CROSS-CONTACT—Continued

Current designation	Nature of proposed change and explanation
§ 110.35(e) (Storage and handling of cleaned portable equipment and utensils).	Clarification. Failure to properly store and handle cleaned portable equipment and utensils could lead to cross-contact of the equipment and utensils and then to cross-contact of food if the equipment and utensils come in contact with food. See section XI.G.6 for the proposed requirement.
§ 110.40(a) (Equipment and utensils)	Clarification. Equipment and utensils that are improperly designed, cleaned and maintained may result in the transfer of food allergens from equipment and utensils to food. See section XI.I for the proposed requirement.
§ 110.40(b) (Equipment and utensils)	Clarification. Equipment and utensils that are improperly designed, cleaned and maintained may result in the transfer of food allergens from equipment and utensils to food. See section XI.I for the proposed requirement.
§ 110.80 (Processes and controls)	Clarification. Inadequate processes and controls practices may result in the transfer of food allergens to food. See section XI.J.1 for the proposed requirement.
§ 110.80 (Processes and controls—General).	Clarification. Inadequate processes and controls practices may result in the transfer of food allergens to food. See section XI.J.1 for the proposed requirement.
§ 110.80(a)(1) (Processes and controls—raw materials and ingredients.).	Clarification. Raw materials and ingredients subject to cross-contact due to improper segregation prior to receipt or during storage may result in undeclared allergens in food. See section XI.J.2 for the proposed requirement.
§ 110.80(a)(5) (Processes and controls—raw materials and ingredients.).	Clarification. Improper handling of raw materials and ingredients may result in the transfer of food allergens to food. See section XI.J.2 for the proposed requirement.
§ 110.80(a)(7) (Processes and controls—raw materials and ingredients.).	Clarification. Improper handling of raw materials and ingredients may result in the transfer of food allergens to food. See section XI.J.2 for the proposed requirement.
N/A	Cross-contact may be associated with improper identification and holding of raw materials and ingredients that are food allergens, and rework that contains food allergens. Improper identification of an allergen-containing raw material, such as a seasoning mix that is not identified as containing soy protein, can result in the unintended incorporation of an allergen into a food (i.e., cross-contact). Improper holding, e.g., storing open-containers of raw materials or ingredients, including those containing allergens, in the same location can result in cross-contact. See section XI.J.2 for the proposed requirement.
§ 110.80(b)(5) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement.
§ 110.80(b)(6) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. Allergens may be transferred from one food to another when raw materials or ingredients are unprotected and allergens in unprotected refuse could contaminate food. Cross-contact can occur when food is conveyed unprotected. See section XI.J.3 for the proposed requirement.
§ 110.80(b)(7) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement.
§ 110.80(b)(10) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement.
§ 110.80(b)(12) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement.
§ 110.80(b)(13) (Processes and controls—manufacturing operations).	Clarification. Manufacturing operations may result in the transfer of food allergens to food. See section XI.J.3 for the proposed requirement.
§ 110.93 (Warehousing and distribution) ...	Clarification. Inadequate storage and transportation conditions may result in the transfer of food allergens to food. See section XI.K for the proposed requirement.

We seek comment on these proposed changes.

E. Proposed and Potential Revisions to Current § 110.10—Personnel (Proposed § 117.10)

1. Proposed Revisions to Current § 110.10(b)—Cleanliness

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.10(b) (Cleanliness), (b)(1) and (b)(9) to make clear that certain provisions involving hygienic practices protect against cross-contact. Proposed § 117.10(b) would require that all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against *cross-contact* and contamination of food (emphasis added). Proposed § 117.10(b)(1) would require that the methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials, *and to protect against the cross-contact of food* (emphasis added). Proposed § 117.10(b)(9) would require taking any other necessary precautions to protect against the contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against the *cross-contact* of food (emphasis added).

As discussed in section XI.A of this document, FDA is proposing to revise current § 110.10(b)(5) to remove the recommendation that gloves be of an impermeable material. Proposed § 117.10(b)(5) would require that the methods for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

2. Potential Revisions to Current § 110.10(c)—Education and Training

Current § 110.10(c) provides guidance that personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

As discussed in section II.A.1 of this document, the CGMP Working Group Report identified specific areas that presented an opportunity to modernize the regulation. One recommendation was to ''require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker'' (Ref. 1). Our analysis of recalls also indicates that ineffective employee training was a root cause of 32 percent of CGMP-related recalls in the 1999–2003 analysis (Ref. 58); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008–2009 analysis (Ref. 59). In addition, as discussed with respect to the proposed definition of preventive controls (see section X.C.4 of this document), section 418(o)(3) of the FD&C Act recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee hygiene training (§ 418(o)(3)(B)) and CGMPs under part 110 (§ 418(o)(3)(F)) as some of the procedures, practices, and processes that may be included as preventive controls.

FDA is proposing to re-establish current § 110.10(c) as proposed § 117.10(c). In addition, as discussed in section XI.M of this document, FDA is requesting comment on how best to revise current § 110.10(c) to implement section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group with respect to training.

3. Proposed Revisions to Current § 110.10(d)—Supervision

Current § 110.10(d) requires that responsibility for ''assuring'' compliance by all personnel with all requirements of part 110 be clearly assigned to competent supervisory personnel. FDA is proposing to revise current § 110.10(d) to replace the term ''assuring'' with ''ensuring'' to clarify FDA's expectation that supervisory personnel make certain that all personnel comply with the CGMP requirements of proposed subpart B. As a grammatical matter, the word ''ensure'' more accurately communicates this expectation than the word ''assure.'' FDA also is proposing to narrow the requirement for supervisory personnel to ensure compliance with proposed part 117, subpart B rather than with all of proposed part 117. Current § 110.10(d) is directed at the requirements already established in part 110 and does not apply to the proposed requirements that would be established in proposed part 117, subpart C. Proposed § 117.10(d) would now state that responsibility for *ensuring* compliance by all personnel with all requirements *of this subpart* must be clearly assigned to competent supervisory personnel (emphasis added).

F. Proposed Revisions to Current § 110.20—Plant and Grounds (Proposed § 117.20)

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.20(b) (Plant Construction and Design) to make two changes for consistency with terms used throughout proposed part 117. Proposed § 117.20(b) would require that the plant buildings and structures be suitable in size, construction, and design to facilitate maintenance and sanitary operations for *food-production purposes (i.e., manufacturing, processing packing, and holding)* and would require that specific construction and design requirements apply to the ''*plant*'' rather than the ''plant and facilities'' (emphasis added).

As discussed in section XI.D of this document, FDA also is proposing to revise current § 110.20(b)(2) and (b)(6) to clarify that plants must be constructed and designed to protect against cross-contact in addition to protecting against the contamination of food. Proposed § 117.20(b)(2) would require that the plant take proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to *reduce the potential for cross-contact* (emphasis added). The potential for *cross-contact* and contamination must be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which *cross-contact* and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means (emphasis added). Separation of operations is a key means of preventing cross-contact. Proposed § 117.20(b)(6) would require that a plant provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for *cross-contact* (emphasis added). Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air currents.

In addition, FDA is proposing to broaden current § 110.20(b)(3) by removing the term ''fermentation'' so that the construction and design requirements to permit the taking of proper precautions to protect food would apply to all outdoor bulk vessels (e.g., fermentation vessels, silos, vessels, and bins) rather than be limited to outdoor bulk fermentation vessels. Outdoor bulk vessels containing food lack the basic protection from environmental factors provided by a building, irrespective of whether the purpose of the outdoor bulk vessel is fermentation or storage. Proposed § 117.20(b)(3) would require that the construction and design of a plant permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means. A conforming editorial change to current § 110.20(b)(3)(iv) would revise ''skimming *the* fermentation vessels'' (emphasis added) to ''skimming fermentation vessels'' to make clear that fermentation vessels would now be only one kind of vessel subject to proposed § 117.20(b)(3).

In addition, as discussed in section XI.C of this document, FDA is proposing to revise current § 110.20(b)(4) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.20(b)(4) would require that the plant be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, *or food-packaging materials* with clothing or personal contact (emphasis added).

G. Proposed Revisions to Current § 110.35—Sanitary Operations (Proposed § 117.35)

1. Proposed Revisions to Current § 110.35(a)—General Maintenance

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.35(a) (General maintenance) to clarify that cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact of food, food-contact surfaces, or food packaging materials in addition to protecting these items against contamination. Proposed § 117.35(a) would require that cleaning and sanitizing of utensils and equipment be conducted in a manner that protects against *cross-contact* and contamination of food, food-contact surfaces, or food-packaging materials (emphasis added).

2. Proposed Revisions to Current § 110.35(b)—Substances Used in Cleaning and Sanitizing; Storage of Toxic Materials

FDA is proposing to revise current § 110.35(b)(1) to emphasize that mechanisms to comply with provisions related to cleaning compounds and sanitizing agents must be safe and effective rather than to emphasize that there are multiple ways to achieve such compliance. With this shift in emphasis, proposed § 117.35(b)(1) would require that cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement *must* be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination (emphasis added). FDA considered whether to delete the examples of mechanisms to achieve compliance as nonbinding recommendations, but tentatively concludes that the examples provide useful information that is suitable in the context in which it remains in the provision.

As discussed in section XI.A of this document, FDA is proposing to revise current § 110.35(b)(2) to remove the recommendation for following all relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of toxic cleaning compounds, sanitizing agents, and pesticide chemicals. FDA tentatively concludes that although such a recommendation may be helpful and could be included in future guidance, it is more properly addressed by the applicable Federal, State, and local government agencies and is outside the scope of proposed part 117.

3. Proposed Revisions to Current § 110.35(c)—Pest Control

FDA is proposing to revise current § 110.35(c) (Pest control) to make a change for internal consistency and clarity as well as to harmonize with terminology used in section 418 of the FD&C Act. Proposed § 117.35(c) would require ''Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the *manufacturing,* processing, *packing and holding* areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials'' (emphasis added).

4. Proposed Revisions to Current § 110.35(d)—Sanitation of Food-Contact Surfaces

FDA is proposing several revisions to current § 110.35(d) (Sanitation of food-contact surfaces). First, FDA is proposing to redesignate current § 110.35(d)(3) as proposed § 117.35(e) (Sanitation of non-food-contact surfaces). Current § 110.35(d)(3) addresses sanitation of non-food-contact surfaces and, thus, does not belong in current § 110.35(d), which addresses sanitation of food-contact surfaces. As a conforming editorial change, current § 110.35(e) would become proposed § 117.35(f).

Second, FDA is proposing to revise current § 110.35(d)(1) to be more explicit that food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean condition at the time of use. Current § 110.35(d)(1) requires that food-contact surfaces used for manufacturing or holding low-moisture food be in a dry, sanitary condition at the time of use; to be sanitary, a food-contact surface must be clean. As discussed in section XI.C of this document, the proposed revision would apply to ''manufacturing/processing'' rather than only to ''manufacturing.'' Proposed § 117.35(d)(1) would require that food-contact surfaces used for *manufacturing/processing* or holding low-moisture food be in a *clean,* dry, sanitary condition at the time of use (emphasis added).

Third, as discussed in section XI.D of this document, FDA is proposing to revise current § 110.35(d) and (d)(2) to address cross-contact and clarify that sanitation of food-contact surfaces must protect against cross-contact of food. Proposed § 117.35(d) would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against *cross-contact* and contamination of food (emphasis added). Proposed § 117.35(d)(2) would require in wet processing, when cleaning is necessary to protect against *cross-contact* and the introduction of microorganisms into food, all food-contact surfaces be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated (emphasis added).

Fourth, as discussed in section XI.C of this document, FDA also is proposing to revise current § 110.35(d)(4) (proposed § 117.35(d)(3)) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. As discussed in section XI.D of this document, FDA also is proposing to revise current § 110.35(d)(4) (proposed § 117.35(d)(3)) to address cross-contact and clarify that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact of food. In addition, in section XI.M of this document, we are requesting comment on whether to require, rather than recommend, that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) be stored in appropriate containers to prevent contamination of food, food-contact surfaces, or food-packaging materials. Proposed § 117.35(d)(3) would provide that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against *cross-contact* and contamination of food, food-contact surfaces, or *food-packaging materials* (emphasis added).

Fifth, FDA is proposing to delete current § 110.35(d)(5), which requires that sanitizing agents be adequate and safe under conditions of use and recommends that cleaning agents be adequate and safe under conditions of use. Current § 110.35(d)(5) is redundant with proposed § 117.35(b)(1), which requires that both cleaning compounds

and sanitizing agents be safe and adequate under the conditions of use.

5. Proposed Revisions to Current § 110.35(d)(3)—Sanitation of Non-Food-Contact Surfaces

As discussed in sections XI.C and XI.D of this document, FDA is proposing to revise current § 110.35(d)(3) (proposed § 117.35(e); sanitation of non-food-contact surfaces) to recommend that such cleaning of non-food contact surfaces protect against cross-contact as well as against contamination and to recommend that such cleaning protect against contamination of food-packaging materials as well as protect against contamination of food and food-contact surfaces. Proposed § 117.35(e) would recommend that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against *cross-contact* and contamination of food, food-contact surfaces, *and food-packaging materials* (emphasis added). In addition, as discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.35(d)(3) (proposed § 117.35(e)) to require, rather than recommend, that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials.

6. Proposed Revisions to Current § 110.35(e)—Storage and Handling of Cleaned Portable Equipment and Utensils

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.35(e) (proposed § 117.35(f); storage and handling of cleaned portable equipment and utensils) to address cross-contact and to recommend storing cleaned and sanitized portable equipment with food-contact surfaces and utensils in a location and manner that protects food-contact surfaces from cross-contact as well as from contamination. Proposed § 117.35(f) would recommend that cleaned and sanitized portable equipment with food-contact surfaces and utensils be stored in a location and manner that protects food-contact surfaces from *cross-contact* and contamination (emphasis added). In addition, as discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.35(e) (proposed § 117.35(f)) to require, rather than recommend, that cleaned and sanitized portable equipment with food-contact surfaces and utensils be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

H. Proposed Revisions to Current § 110.37—Sanitary Facilities and Controls (Proposed § 117.37)

1. Proposed Revisions to Current § 110.37(a)—Water Supply

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.37(a) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(a) would require that the water supply be sufficient for the operations intended and be derived from an adequate source. Any water that contacts food, food-contact surfaces, *or food-packaging materials* must be safe and of adequate sanitary quality (emphasis added). Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

2. Proposed Revisions to Current § 110.37(d)—Toilet Facilities

Current § 110.37(d) requires that each plant provide its employees with adequate, readily accessible toilet facilities and provides recommendations for how compliance with the requirements may be accomplished. These recommendations address issues such as the sanitary and overall physical condition of the toilet facilities, as well as the type and location of toilet facilities' doors.

We considered whether to revise current § 110.37(d) to require, rather than recommend, specific provisions for achieving compliance with the requirements for toilet facilities. In doing so, we considered comments received in response to proposed bathroom requirements contained in the proposed rule to establish CGMP requirements for dietary supplements (the dietary supplement proposed rule; 68 FR 12158 at 12254). The dietary supplement proposed rule would have established—as requirements—provisions similar to the recommendations in current § 110.37(d). Comments on these proposed bathroom requirements stated that firms should be given flexibility in designing their bathrooms (72 FR 34752 at 34817). FDA agreed that it is unnecessary to require specific bathroom features because firms may be able to achieve compliance through means better suited to their operations. The final rule replaced requirements for specific bathroom features with more general requirements for providing employees with adequate, readily accessible bathrooms, and for bathrooms to be kept clean and not be a potential source of contamination to components, dietary supplements, or contact surfaces (§ 111.15(h)).

We tentatively conclude that revising current § 110.37(d) to establish a performance standard for toilet facilities similar to the one found in § 111.15(h) is a better approach than mandating the recommendations in current § 110.37(d). Consistent with the discussion in section XI.C of this document, the proposed performance standard would be directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(d) would maintain the current requirement that each plant provide its employees with adequate, readily accessible toilet facilities. In addition, proposed § 117.37(d) would require that toilet facilities be kept clean and not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

3. Proposed Revisions to Current § 110.37(e)—Hand-washing Facilities

Current § 110.37(e) requires that hand-washing facilities be adequate and convenient and be furnished with running water at a suitable temperature and provides recommendations for how compliance with the requirements may be accomplished. These recommendations address issues such as providing hand-washing and hand-sanitizing facilities, hand-cleaning and sanitizing preparations, towel service or suitable drying devices, water control valves, appropriate signs and refuse receptacles that are properly constructed and maintained.

We considered whether to revise current § 110.37(e) to require, rather than recommend, mechanisms for achieving compliance with the requirements for hand-washing facilities. In doing so, we considered comments received in response to proposed hand-washing facility requirements contained in the dietary supplement proposed rule (68 FR 12158 at 12254). The dietary supplement proposed rule would have established—as requirements—provisions similar to the recommendations in current § 110.37(e). Comments on these proposed hand-washing facility requirements stated that firms should be given flexibility to design their hand-

washing facilities and that an overall sanitation requirement should be sufficient (72 FR 34752 at 34818). FDA agreed that it is unnecessary to require specific hand-washing mechanisms because firms may be able to achieve compliance through other means better suited for their operations; however, we disagreed that an overall sanitation requirement would be sufficient because such a requirement would not clearly state the purpose of the requirement, which is to ensure that an employee's hands are not a source of contamination. The final rule replaced requirements for specific hand-washing facility features with more general requirements for providing hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature (§ 111.15(i)).

We tentatively conclude that establishing a performance standard for hand-washing facilities similar to the one found in § 111.15(i) is a better approach than mandating the current recommendations in § 110.37(e). Consistent with the discussion in section XI.C of this document, the proposed performance standard would be directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(e) would require that each plant provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

4. Proposed Revisions to Current § 110.37(f)— Rubbish and Offal Disposal

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.37(f) so that it is directed to preventing contamination of food-packaging materials as well as food and food-contact substances. Proposed § 117.37(f) would require that rubbish and any offal be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, *food-packaging materials,* water supplies, and ground surfaces (emphasis added).

I. Proposed Revisions to Current § 110.40—Equipment and Utensils (Proposed § 117.40)

FDA is proposing to reorganize the provisions found in current § 110.40(a) by creating paragraph designations (1) through (6) with associated editorial changes. This is a non-substantive revision to make it easier to see the distinct requirements. As discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.40(a) to require, rather than recommend, that all equipment be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces (proposed § 117.40(a)(3)).

As discussed in section XI.D of this document, FDA is proposing to (1) revise current § 110.40(a) (in proposed § 117.40(a)(5)) to clarify that all plant equipment and utensils must protect against cross-contact in addition to the contamination of food and (2) revise current § 110.40(b) to clarify that seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize the opportunity for cross-contact. Proposed § 117.40(a)(5) would require that food-contact surfaces be maintained to protect food from *cross-contact* and from being contaminated by any source, including unlawful indirect food additives (emphasis added). Proposed § 117.40(b) would require that seams on food-contact surfaces be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and *cross-contact* (emphasis added).

As discussed in section XI.A of this document, FDA is proposing to delete the recommendation in current § 110.40(e) that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation. Proposed § 117.40(e) would require that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

FDA is proposing to revise current § 110.40(f) to require that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food be precise as well as accurate. By using the word ''precise'' we mean that individual measurements must be close to each other when made under the same conditions so that the variation in measurements is not statistically significant. An instrument that gives widely varying readings from one use to the next cannot be consistently accurate and therefore cannot ensure product safety over time. The proposed requirement for such instruments and controls to be precise as well as accurate would be consistent with the requirements in the dietary supplement GMPs (§ 111.27(a)(6)(i)), which were established after the requirements in current § 110.40(f). Proposed § 117.40(f) would require that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food be accurate and *precise* and adequately maintained, and adequate in number for their designated uses (emphasis added).

J. Proposed Revisions to Current § 110.80—Processes and Controls (Proposed § 117.80)

1. Proposed Revisions to Current § 110.80

FDA is proposing to reorganize the provisions found in six sentences that precede current § 110.80(a) by creating paragraph designations (a)(1) through (6) with associated editorial changes, including the title ''General'' for new paragraph (a) of proposed § 117.80. This is a non-substantive revision to make it easier to see the distinct requirements and to clearly identify each requirement with a paragraph citation. As corresponding changes, current § 110.80(a) would become proposed § 117.80(b) and current § 110.80(b) would become proposed § 117.80(c).

As discussed in section XI.D of this document, FDA is proposing to revise two provisions to current § 110.80 to clarify that certain practices involving processes and controls must protect against cross-contact. Proposed § 117.80(a)(4), in relevant part, would require that reasonable precautions be taken to ensure that production procedures do not contribute to *cross-contact* and contamination from any source (emphasis added). Proposed § 117.80(a)(5) would require that chemical, microbial, or extraneous-material testing procedures be used where necessary to identify sanitation

failures or possible *cross-contact* and food contamination (emphasis added).

2. Proposed Revisions to Current § 110.80(a)—Raw Materials and Other Ingredients

As discussed in section XI.D of this document, FDA is proposing a number of revisions to current § 110.80(a) (i.e., to current § 110.80(a)(1), (a)(5), and (a)(7)) to clarify that certain practices involving raw materials and ingredients must protect against cross-contact. As discussed in section XI.D of this document, FDA also is proposing to clarify that three of the five separate statements within current § 110.80(a)(1) address cross-contact as well as contamination. Proposed § 117.80(b)(1) would require, in relevant part, that raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and be stored under conditions that will protect against *cross-contact* and contamination, and minimize deterioration (emphasis added). Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or *cause cross-contact (emphasis added).* Proposed § 117.80(b)(1) would continue to recommend that containers and carriers of raw materials *should* be inspected on receipt to ensure that their condition has not contributed to *cross-contact,* contamination, or deterioration of food (emphasis added). As discussed in section XI.M of this document, FDA also is requesting comment on whether to revise current § 110.80(a)(1) to require, rather than recommend, that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to the cross-contact, contamination or deterioration of food.

Current § 110.80(a)(2) requires that raw materials and other ingredients either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. FDA is proposing to revise current § 110.80(a)(2) by replacing the phrase ''may produce food poisoning or other disease in humans'' with ''may render the food injurious to the health of humans.'' The proposed revision would align the provision with the adulteration provision in section 402(a)(4) of the FD&C Act. As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(2). Proposed § 117.80(b)(2) would require that raw materials and ingredients either not contain levels of microorganisms that *may render the food injurious to the health of* humans, or they be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated (emphasis added).

Current § 110.80(a)(3) requires that raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins comply with current FDA regulations and *action levels* for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. An action level for an added poisonous or deleterious substance may be established to define a level of contamination at which a food may be regarded as adulterated (§ 109.4) (21 CFR 109.4). In 1990, we issued a final rule to revise part 109 to clarify that action levels constitute prosecutorial guidance rather than substantive rules (55 FR 20782, May 21, 1990). Because action levels themselves constitute guidance, revising current § 110.80(a)(3) to reflect that action levels are nonbinding would be duplicative and unnecessary and FDA is proposing to delete the current requirement for compliance with action levels from current § 110.80(a)(3). Importantly, the proposed deletion merely reflects an administrative practice to limit the number of recommendations we include in our regulations; we continue to regard action levels as an important approach to food safety. As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(3). Proposed § 117.80(b)(3) would require that raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins comply with current Food and Drug Administration regulations for poisonous or deleterious substances before these materials or *ingredients* are incorporated into finished food (emphasis added).

Current § 110.80(a)(4) requires that raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable FDA regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Defect action levels are guidance for natural or unavoidable defects in food for human use that present no health hazard (Ref. 141). FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action (Ref. 141). As discussed above in this section, in 1990, we issued a final rule to revise part 109 to clarify that action levels are prosecutorial guidance rather than substantive rules (55 FR 20782). Because defect action levels themselves constitute guidance, revising current § 110.80(a)(4) to reflect that action levels are nonbinding would be duplicative and unnecessary. Therefore, FDA is proposing to delete the current requirement for compliance with defect action levels in current § 110.80(a)(4). As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(a)(4). Proposed § 117.80(b)(4) would require raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable Food and Drug Administration regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.80(a)(5) to clarify that raw materials, ingredients, and rework be held in bulk, or in containers designed and constructed so as to protect against *cross-contact* as well as against contamination. Proposed § 117.80(b)(5) would require that raw materials, ingredients, and rework be held in bulk, or in containers designed and constructed so as to protect against *cross-contact* and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such. (Emphasis added.)

As discussed in section XI.D of this document, FDA is proposing to revise current § 110.80(a)(7) to clarify that liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact as well as contamination. Proposed § 117.80(b)(7) would require that liquid or dry raw materials and ingredients received and stored in bulk form be held in a manner that protects against *cross-contact* and contamination (emphasis added).

As discussed in section XI.D of this document, FDA is proposing to establish a new requirement in current

§ 110.80(a) regarding cross-contact. Proposed § 117.80(b)(8) would require that raw materials and ingredients that are food allergens, and rework that contains food allergens, be identified and held in a manner that prevents cross-contact. We seek comment on this proposal.

3. Proposed Revisions to Current § 110.80(b)—Manufacturing Operations

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.80(b)(2) by replacing the phrase ''manufacturing, including packaging and storage'' with ''manufacturing, processing, packing and holding.'' As discussed in section XI.A of this document, FDA also is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(b)(2). Proposed § 117.80(c)(2) would require that all food manufacturing, *processing, packing* and *holding,* be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food (emphasis added).

Current § 110.80(b)(3) requires that food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, be held in a manner that prevents the food from becoming adulterated within the meaning of the FD&C Act and provides recommendations for complying with this requirement. FDA is proposing a series of revisions to current § 110.80(b)(3). Specifically, FDA is proposing to:

- Replace the phrase ''in a manner'' with ''at temperatures'' to identify a specific manner in which food that supports the rapid growth of microorganisms must be held—i.e., through temperature control. Temperature control is generally recognized as essential to food safety for foods that can support the rapid growth of microorganisms (Ref. 137) (Ref. 138) (Ref. 139) (Ref. 140).
- Include the phrase ''during manufacturing, processing, packing and holding'' to emphasize that temperature controls do not end with the manufacturing/processing phase, but extend through packing and holding.
- Delete the recommendations in current § 110.80(b)(3)(i) through (iv). (See the discussion of the proposed deletion in section XI.A of this document.)

With these changes, proposed § 117.80(c)(3) would require that food that can support the rapid growth of undesirable microorganisms be held *at temperatures* that will prevent the food from becoming adulterated, *during manufacturing, processing, packing and holding* (emphasis added).

Current § 110.80(b)(4) requires that measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act. FDA is proposing to include ''cooking'' as an additional such measure. Cooking, if done adequately, is well accepted as a mechanism of destroying microorganisms (Ref. 142). FDA also is proposing to delete the phrase ''particularly those of public health significance'' because it is redundant with the proposed definition for the term ''microorganisms'' (proposed § 117.3), which identifies microorganisms of public health significance as a type of undesirable microorganism, and therefore is unnecessary. Proposed § 117.80(c)(4) would require measures such as sterilizing, irradiating, pasteurizing, *cooking,* freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated (emphasis added).

Current § 110.80(b)(5) requires that work-in-process be handled in a manner that protects against contamination. FDA is proposing to revise current § 110.80(b)(5) to require handling in a manner to protect against the growth of undesirable microorganisms. The growth of any undesirable microorganisms already present in a food, such as pathogenic sporeformers, must be controlled, as well as protecting the food against the introduction of contaminants. As discussed in section XI.D of this document, FDA also is proposing to clarify that work-in-process must be handled in a manner to protect against cross-contact. In addition we are proposing to revise current § 110.80(b)(5) to broaden the provision to include ''rework.'' The term ''rework'' would be defined in proposed § 117.3 to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. As with work-in-process, improper handling of rework could result in cross-contact, contamination, or growth of undesirable microorganisms. Proposed § 117.80(c)(5) would require that work-in-process and *rework* be handled in a manner that protects against *cross-contact,* contamination, and *growth of undesirable microorganisms* (emphasis added).

As discussed in section XI.D of this document, FDA is proposing to clarify that three provisions in current § 110.80(b)(6) require that effective measures be taken to protect finished food from cross-contact as well as from contamination. Proposed § 117.80(c)(6) would require that effective measures be taken to protect finished food from *cross-contact* and contamination by raw materials, ingredients, or refuse (emphasis added). When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in *cross-contact* or contaminated food (emphasis added). Food transported by conveyor must be protected against *cross-contact* and contamination as necessary (emphasis added).

As discussed in section XI.D of this document, FDA is proposing to clarify that current § 110.80(b)(7) requires that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing or storage in a manner that protects against cross-contact as well as against contamination. As discussed in section XI.C of this document, FDA also is proposing to replace the term ''storage'' with the term ''holding'' for consistency with use of the term ''holding'' throughout proposed part 117 and to add processing and packing as activities where protection is needed against contamination and cross-contact. Proposed § 117.80(c)(7) would require that equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing, *processing, packing and holding* in a manner that protects against *cross-contact and* contamination (emphasis added).

As discussed in section XI.A of this document, FDA is proposing to delete guidance regarding how to comply with the requirements of current § 110.80(b)(8). Proposed § 117.80(c)(8) would require that effective measures be taken to protect against the inclusion of metal or other extraneous material in food.

Current § 110.80(b)(9) requires that food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. It further requires that if the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective or it be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food. FDA is proposing to delete the option for reexamination so that adulterated food can only be disposed of or reconditioned if the food is capable of being reconditioned. FDA is proposing this deletion because a food may test positive for a contaminant in one test and negative in one or more additional tests although the food continues to be contaminated. For example, the distribution of a pathogen in a food may not be homogeneous. Therefore, a food found to be adulterated must be reconditioned before it is reexamined. FDA also is proposing to combine the two sentences in current § 110.80(b)(9) with an ''or'' to make clear that reconditioning, rather than disposal, is an option. Proposed § 117.80(c)(9) would require food, raw materials, and ingredients that are adulterated be disposed of in a manner that protects against the contamination of other food *or, if* the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective (emphasis added).

Current § 110.80(b)(10) requires that mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. FDA is proposing to revise current § 110.80(b)(10) to replace the phrase ''mechanical manufacturing steps'' with the single term ''steps'' because ''mechanical manufacturing'' does not accurately describe all steps listed in the current provision. Current § 110.80(b)(10) also includes three recommendations. As discussed in section XI.A of this document, FDA is proposing to delete two of these recommendations (regarding adequate cleaning and sanitizing of all food-contact surfaces and regarding the use of time and temperature controls). As discussed in section XI.D of this document, FDA also is proposing to clarify that steps identified in current § 110.80(b)(10) require protection against cross-contact. Proposed § 117.80(c)(10) would require that *steps* such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming be performed so as to protect food against *cross-contact* and contamination and would continue to recommend that food should be protected from contaminants that may drip, drain, or be drawn into the food (emphasis added). As discussed in section XI.M of this document, FDA is requesting comment on whether to establish the third recommendation (regarding physical protection of food from contaminants that may drip, drain, or be drawn into the food) as a requirement.

Current § 110.80(b)(11) requires, in relevant part, that where a blanched food is washed prior to filling, water used be safe and of adequate sanitary quality. FDA is proposing to delete this requirement because water quality would already be addressed in proposed § 117.37(a) and would be redundant in proposed § 117.80(c)(11). Current § 110.80(b)(11) also recommends that heat blanching, when required in the preparation of food, be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. As discussed in section XI.M, of this document, FDA is requesting comment on whether to establish this recommendation as a requirement. Current § 110.80(b)(11) also recommends that thermophilic growth and contamination in blanchers be minimized by the use of adequate operating temperatures and by periodic cleaning. As discussed in section XI.M of this document, FDA is requesting comment on whether to establish this recommendation as a requirement. Proposed § 117.80(c)(11) would continue to recommend that heat blanching, when required in the preparation of food, *should* be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay (emphasis added). Proposed § 117.80(c)(11) also would continue to recommend that thermophilic growth and contamination in blanchers *should* be minimized by use of adequate operating temperatures and by periodic cleaning (emphasis added).

Current § 110.80(b)(12) requires that batters, breading, sauces, gravies, dressings, and other similar preparations be treated or maintained in such a manner that they are protected against contamination and provides several recommendations for how to comply with this requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. As discussed in section XI.D of this document, FDA also is proposing to clarify that steps identified in current § 110.80(b)(12) require protection against cross-contact. Proposed § 117.80(c)(12) would require that batters, breading, sauces, gravies, dressings, and other similar preparations be treated or maintained in such a manner that they are protected against *cross-contact* and contamination (emphasis added).

Current § 110.80(b)(13) requires that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against contamination. FDA is proposing to revise current § 110.80(b)(13) to require that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against the growth of undesirable microorganisms as well as against contamination. The growth of any undesirable microorganisms already present in a food must be controlled, in addition to the introduction of contaminants. Current § 110.80(b)(13) also includes several recommendations for achieving compliance. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. As discussed in section XI.D of this document, FDA also is proposing to require protection against cross-contact. Proposed § 117.80(c)(13) would require that filling, assembling, packaging, and other operations be performed in such a way that the food is protected against *cross-contact,* contamination, and *growth of undesirable microorganisms* (emphasis added).

Current § 110.80(b)(14) requires that food, such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms be processed to and maintained at a safe moisture level. Current § 110.80(b)(14) also provides recommendations for accomplishing compliance with this requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. Proposed § 117.80(c)(14) would require that food, *including* dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable

microorganisms be processed to and maintained at a safe moisture level (emphasis added).

Current § 110.80(b)(15) requires that food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below and includes two recommendations for how to comply with the requirement. As discussed in section XI.A of this document, FDA is proposing to delete these recommendations. Proposed § 117.80(c)(15) would require food, *including* acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below.

K. Proposed Revisions to Current § 110.93—Warehousing and Distribution (Proposed § 117.93)

Current § 110.93 requires that storage and transportation of finished food be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. FDA is proposing a series of revisions to current § 110.93.

FDA is proposing to delete the term ''finished'' before ''food'' because the requirements in this provision must apply to all food being held for distribution regardless of whether it is a raw material or ingredient or in its finished state. To ensure food safety throughout the food chain, food, whether a raw material or finished product, must be protected against contamination.

As discussed in section XI.D of this document, FDA also is proposing to revise § 110.93 to clarify that storage and transportation of food must be under conditions that will protect against cross-contact of food in addition to protecting against contamination of food.

FDA also is proposing to add radiological hazards as an additional category of contaminants to the list of contaminants which may be encountered in warehousing and distribution because food may be subject to contamination with radiological hazards. As discussed in section XII.B, FDA now recognizes four types of hazards: biological, chemical, physical and radiological. Our CGMP regulation for bottled water in part 129 requires plants to analyze product samples for bacteriological, chemical, physical and radiological purposes (§ 129.80(g)). Therefore, the proposed addition of radiological contaminants to the list of contaminants would be consistent with part 129. FDA tentatively concludes that there is no basis for requiring a facility to protect against some types of hazards but not others, and thus is proposing to include radiological hazards among those from which food must be protected.

FDA also is proposing to require protection against ''biological,'' rather than ''microbial'' contamination of food so that, when a provision specifies all four types of hazards that must be addressed, the list is presented consistently throughout proposed part 117. In section XII.B.3 of this document, we discuss a requirement, which would be established in proposed § 117.130(b), for a hazard analysis to address biological, chemical, radiological, and physical hazards. FDA also is proposing to present the list of types of hazards in the same order as the list would be presented in proposed § 117.130(b).

Proposed § 117.93 would require that storage and transportation of food be under conditions that will protect against *cross-contact* and *biological,* chemical, physical, and *radiological* contamination of food as well as against deterioration of the food and the container (emphasis added).

L. Proposed Revisions to Current § 110.110—Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard (Proposed § 117.110)

As discussed in section XI.C of this document, FDA is proposing to revise current § 110.110(c) to change the designated persons who must ''observe good manufacturing practices'' and ''at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible'' from the currently identified persons (i.e., manufacturers, distributors and holders of food) to manufacturers, processors, packers and holders of food. FDA also is proposing to update the reference in current § 110.110(c) to section 402(a)(4) of the FD&C Act to make it more complete by specifying that the insanitary conditions are those whereby food may have become contaminated with filth, or whereby food may have been rendered injurious to health. Proposed § 117.110(c) would specify that compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions *whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health,* or the requirements in part 117 that food *manufacturers, processors, packers, and holders* must observe current good manufacturing practice (emphasis added). Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

FDA is proposing to revise current § 110.110(d) to replace the clause ''The mixing of a food containing defects above the current defect action level * * *'' with ''The mixing of a food containing defects at levels that render the food adulterated * * *'' We are proposing this change to clarify that food containing defects above the current defect action level is not automatically adulterated under the FD&C Act. A defect action level is nonbinding and is directed to a natural or unavoidable defect in food that presents no health hazards for humans (Ref. 141). Whether food containing defects above the current defect action levels adulterate the food is a case-by-case determination that depends on the circumstances. Proposed § 117.110(d) would specify that the mixing of a food containing defects *at levels that render that food adulterated* with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food (emphasis added).

As discussed in section XI.A of this document, FDA is proposing to delete current § 110.110(e), which provides that a compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request.

M. Potential Revisions To Establish Requirements in Place of Current Guidance

1. Overview

In sections IX.F and XI.A of this document, we discuss our intent to delete some non-binding provisions of current part 110 (e.g., provisions using ''should'' or ''compliance may be achieved by''). In this section of this document, we request comment on whether to revise other non-binding provisions to establish new requirements in proposed part 117 or retain them as useful recommendations of a comprehensive CGMP provision.

We discuss each of these immediately below.

We believe that these CGMP provisions are science-based and an important part of a modern food safety system. Because these non-binding provisions have been in place for decades, they are widely used and commonly accepted in many sectors of the food industry. In addition, under section 418(o)(3) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include sanitation procedures for food contact surfaces of utensils and equipment; supervisor, manager, and employee hygiene training; and CGMPs under part 110 of title 21 (or any successor regulations).

The vast majority of the costs related to a revised mandatory sanitary operations, process and controls program would be for the time that workers are in training for the alternative requirements rather than in production. We estimate that this alternative, when implemented as part of a preventive approach, could impose an incremental annual cost of $560–$28,000 per facility based on size (number of employees) to facilities that do not already comply with this alternative. This would result in an estimated aggregate cost of $16 million for domestic facilities and an estimated aggregate cost of $17,400,000 for foreign facilities. This estimate assumes that about half of the qualified facilities would need to review their operations and perform the training. Most non-qualified facilities would have met the requirements by following the requirements for sanitation controls in subpart C but for those that do not have hazards that are reasonably likely to occur or for those with sanitation controls that do not fully address the requirements of the sanitary operations, they would need to review their operations and perform the training. Further details are provided in the ''Consideration of Other Provisions'' section of the RIA.

2. Summary of Potential Revisions To Establish Requirements in Place of Current Guidance

Table 11 identifies each of the potential revisions to establish new requirements and either explains the reason for establishing the requirement or, for such revisions with longer explanations, refers to the section of this document where the potential requirement is explained.

TABLE 11—POTENTIAL REVISIONS TO ESTABLISH REQUIREMENTS IN PLACE OF CURRENT GUIDANCE

Designation of proposed provision	Potential additional revision to establish a requirement in place of a recommendation (emphasis added)	Basis for potential revision
§ 117.10(c)	Personnel responsible for identifying sanitation failures or food contamination *must* have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors *must* receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.	See explanation and questions about whether more detail would be appropriate in section XI.M.3 of this document.
§ 117.35(d)(3) (Sanitation of food-contact substances).	Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) *must* be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.	Failure to properly store such articles could lead to contamination of the articles and then to contamination of food if the articles come in contact with food.
§ 117.35(e) (Sanitation of non-food-contact substances).	Non-food-contact surfaces of equipment used in the operation of a food plant *must* be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food and food-contact surfaces.	Failure to clean non-food-contact surfaces could lead to contamination of food-contact surfaces of the equipment and utensils and then to contamination of food if the contaminated equipment and utensils come in contact with food. For example, cleaning non-food-contact surfaces is essential to prevent contamination of food from environmental pathogens such as *L. monocytogenes* and *Salmonella* spp.
§ 117.35(f) (Storage and handling of cleaned portable equipment and utensils).	Cleaned and sanitized portable equipment with food-contact surfaces and utensils *must* be stored in a location and manner that protects food-contact surfaces from contamination.	Failure to properly store and handle such equipment and utensils could lead to contamination of the equipment and utensils and then to contamination of food if the equipment and utensils come in contact with food.
§ 117.40(a)(1) (Equipment and utensils).	All equipment must be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.	Failure to properly clean equipment and adjacent spaces due to improper installation and maintenance could lead to contamination of the equipment and then contamination of food if the equipment comes in contact with the food.
§ 117.80(b)(1) (Processes and controls—raw materials and ingredients).	Containers and carriers of raw materials *must* be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.	Containers and carriers of raw materials not properly maintained can lead to contamination or deterioration of food.
§ 117.80(c)(10) (Manufacturing operations).	Food *must* be protected from contaminants that may drip, drain, or be drawn into the food during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming.	There are no circumstances where it would not be necessary to provide adequate physical protection of food from contaminants that may drip, drain, or be drawn into food.

TABLE 11—POTENTIAL REVISIONS TO ESTABLISH REQUIREMENTS IN PLACE OF CURRENT GUIDANCE—Continued

Designation of proposed provision	Potential additional revision to establish a requirement in place of a recommendation (emphasis added)	Basis for potential revision
§ 117.80(c)(11) (Manufacturing operations).	Heat blanching, when required in the preparation of food, *must* be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay.	Properly heating and cooling food during blanching is necessary to protect food from contamination and would apply in all cases for food when heat blanching is required in the preparation.
§ 117.80(c)(11) (Manufacturing operations).	Thermophilic growth and contamination in blanchers *must* be minimized by the use of adequate operating temperatures and by periodic cleaning.	Adequate operating temperatures and proper cleaning are necessary for controlling growth of thermophilic bacteria and contamination and would apply in all cases for food when heat blanching is required in the preparation.

3. Potential Revisions To Establish Requirements in Place of Current Guidance for Education and Training

Current § 110.10(c) provides guidance that personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Current § 110.10(c) further recommends that food handlers and supervisors receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

As discussed in section II.A.1 of this document, the CGMP Working Group Report identified specific areas that presented an opportunity to modernize the regulation. One recommendation was to ''require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker'' (Ref. 1). Our analysis of recalls also indicates that ineffective employee training was a root cause of 32 percent of CGMP-related recalls in the 1999–2003 analysis (Ref. 58); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008–2009 analysis (Ref. 59). In addition, as discussed with respect to the proposed definition of preventive controls (see section X.C.4 of this document), section 418(o)(3) of the FD&C Act recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee hygiene training (§ 418(o)(3)(B)) and CGMPs under part 110 (§ 418(o)(3)(F)) as some of the procedures, practices, and processes that may be included as preventive controls.

The vast majority of costs related to a mandatory education and training program would be for the time that workers would be training rather than in production. We estimate that a requirement for education and training, when implemented as part of a preventive approach, could impose an incremental annual cost of $1,000–$25,000 per facility based on size (number of employees) to facilities that do not already conduct training. This would result in an estimated aggregate cost of $93 million for domestic facilities and an estimated aggregate cost of $101,300,000 for foreign facilities. This estimate assumes that both qualified and nonqualified facilities would be required to perform the training. Further details are provided in the ''Consideration of Other Provisions'' section of the RIA.

We request comment on how best to revise current § 110.10(c) in light of section 418(o)(3) of the FD&C Act and the recommendations of the CGMP Working Group with respect to training. Should we replace the current recommendations for personnel education and experience with requirements? Doing so would be consistent with the emphasis in section 418(o)(3) of the FD&C Act on the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls and with the recommendation in the CGMP Working Group Report. If so, what is the appropriate level of specificity? For example, should we simply replace the ''shoulds'' in current § 110.10(c) with ''musts''? This would provide flexibility for each establishment to determine the type and frequency of education and training appropriate for its personnel.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying that each person engaged in food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) receive training as appropriate to the person's duties;
- Specifying the frequency of training (e.g., upon hiring and periodically thereafter);
- Specifying that training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility; and
- Specifying that records document required training of personnel and, if so, specifying minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained).

We also request comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both. If we establish a requirement for education and training in subpart B, that requirement would apply to all persons who manufacture, process, pack or hold food, with the exceptions of persons who would be exempt from subpart B (i.e., under proposed § 117.5(k), a requirement in subpart B would not apply to ''farms'', activities of ''farm mixed-type facilities'' that fall within the definition of ''farm,'' or the holding or transportation of one or more RACs). On the other hand, if we establish a requirement for education and training in subpart C, that requirement would not apply to persons who would be exempt from the requirements of proposed subpart C (e.g., qualified facilities and persons conducting activities subject to HACCP regulations for juice or seafood).

N. Request for Comment on Additional CGMP Requirements

We request comment on any additional proposed revisions or clarifications to our CGMP regulations that should be included in subpart B, including whether to further implement the ''opportunities'' for CGMP modernization identified by the CGMP Working Group or to enhance the CGMP regulations in some other way. For example, we request comment on whether a final rule based on this proposed rule should include CGMP requirements for environmental monitoring for *L. monocytogenes,* and whether such requirements should include other environmental pathogens such as *Salmonella* spp. If so, we also request comment on what such requirements should be. For additional information on environmental monitoring for *L. monocytogenes* and *Salmonella* spp., see sections I.D and I.E of the Appendix to this document.

XII. Proposed New Requirements for Hazard Analysis and Risk-Based Preventive Controls (Proposed Part 117, Subpart C)

A. Proposed § 117.126—Requirement for a Food Safety Plan

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act requires that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also requires that such written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 117.126(a)—Requirement for a Food Safety Plan

Proposed § 117.126(a) would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, and implement a written food safety plan. We use the term ''written food safety plan'' in proposed § 117.126(a) to mean the ''written plan'' referred to in section 418(h) of the FD&C Act. To make clear that the written plan is related to food safety rather than to other plans a facility may have (such as quality control plans or food defense plans), we have designated the ''written plan'' to be a ''food safety plan.''

Proposed § 117.126(a) would require that the plan be written as is expressly required by section 418(h). A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. It is also essential to a facility's food safety team, to auditors, and to inspectors. Proposed § 117.126(a) would implement section 418(h) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The recordkeeping provisions of the NACMCF HACCP guidelines recommend that the HACCP plan include a list of the HACCP team and assigned responsibilities; a description of the food, its distribution, intended use, and consumer; a verified flow diagram; a HACCP Plan Summary Table that includes information for steps in the process that are CCPs, the hazard(s) of concern, critical limits, monitoring, corrective actions, verification procedures and schedule, and record-keeping procedures (Ref. 34). The Codex HACCP Annex recommends that HACCP procedures be documented, including the hazard analysis, and determinations of CCPs and critical limits (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require a written plan (§§ 123.6(b)) and 120.8(a) and 9 CFR 417.2(b), respectively).

Proposed § 117.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf. This flexibility is consistent with the NACMCF HACCP guidelines (Ref. 34), which advise that a HACCP team may need assistance from outside experts who are knowledgeable in the hazards associated with the product and the process. This flexibility also is consistent with the Codex HACCP Annex, which acknowledges that small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan and recommends that expert advice be obtained when necessary from other sources, such as trade and industry associations, independent experts and regulatory authorities. In addition, proposed § 117.126 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical.

Proposed § 117.126(a) would require that the owner, operator, or agent in charge of a facility implement the written food safety plan. Although section 418(h) of the FD&C Act is silent with respect to implementation of the required written plan, other provisions of section 418 address implementation. For example, section 418(c) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility both establish *and implemen*t preventive controls (emphasis added). In addition, other provisions of section 418 (e.g., section 418(d) regarding monitoring, section 418(e) regarding corrective actions, and section 418(f) regarding verification) all establish requirements related to the preventive controls required under section 418(c). As discussed immediately below, the written food safety plan would include the hazard analysis required under section 418(b) of the FD&C Act, the preventive controls required under section 418(c) of the FD&C Act, the monitoring procedures required under section 418(d) of the FD&C Act, the corrective action procedures required under section 418(e) of the FD&C Act, the verification procedures required under section 418(f) of the FD&C Act, and the recall plan as authorized by section 418(o)(3)(E) of the FD&C Act. Specific provisions for implementing these sections of the statute would be established throughout proposed subpart C.

3. Proposed § 117.126(b)—Contents of a Food Safety Plan

Proposed § 117.126(b)(1) through (6) would require that the contents of a food safety plan include:

- The written hazard analysis as required by proposed § 117.130(a)(2);
- The written preventive controls as required by proposed § 117.135(b);
- The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by proposed § 117.140(a);
- The written corrective action procedures as required by proposed § 117.145(a)(1);
- The written verification procedures as required by proposed § 117.150(e); and
- The written recall plan as required by § 117.137(a).

Section 418(h) requires that the written plan document and describe the

procedures used by the facility to comply with the requirements of section 418, ''*including* analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards'' (emphasis added). Although section 418(h) of the FD&C Act explicitly references sections 418(b) and (c), the term ''including,'' indicates that the contents of a food safety plan need not be limited to the provisions of sections 418(b) and (c) of the FD&C Act.

FDA interprets the requirement in section 418(h) of the FD&C Act that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act to mean that the written food safety plan would include all procedures required under section 418 of the FD&C Act. As discussed in sections XII.E.6.a, XII.F.2, XII.G.6, and XII.D.2 of this document, the proposed rule would require written procedures for monitoring the implementation of the preventive controls (proposed § 117.140(a)); written corrective action procedures (proposed § 117.145(a)(1)); written procedures for some verification activities (proposed § 117.150(e)); and a written recall plan (proposed § 117.137(a)).

FDA interprets the requirement in section 418(h) that the written plan describe the procedures used by the facility to comply with the requirements of section 418, including analyzing the hazards and identifying the preventive controls adopted to address those hazards, to mean that the contents of the food safety plan must include the hazard analysis conducted by the facility and the preventive controls that a facility must establish for hazards that its hazard analysis identifies as reasonably likely to occur, rather than procedures for analyzing the hazards and procedures for identifying the preventive controls. The general requirement in section 418(a) of the act is directed, in relevant part, to evaluating the hazards that could affect food manufactured, processed, packed, or held by a facility, and identifying and implementing preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Review of the evaluation of hazards in the hazard analysis is sufficient to determine the adequacy of the hazard analysis. Written procedures for conducting the hazard analysis are not necessary. Similarly, the preventive controls identified by the facility can be reviewed fully for adequacy without having a separate procedures document.

Under our interpretation of section 418(h) of the FD&C Act, proposed § 117.126(b)(1) and (2) are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that a HACCP plan include the hazards of concern (which are the end product of the hazard analysis), the CCPs (which are the steps at which control can be applied and which are essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level), and critical limits (which are the maximum or minimum values established at a CCP to control a hazard) (Ref. 34). The Codex HACCP Annex (Ref. 35) recommends that the HACCP plan include documentation of the hazard analysis and determinations of CCPs and critical limits. Federal HACCP regulations for seafood, juice, and meat and poultry all require that the HACCP plan list the food [safety] hazards that are reasonably likely to occur (§§ 123.6(c)(1) and 120.8(b)(1) and 9 CFR 417.2(c)(1), respectively), the CCPs (§§ 123.6(c)(2) and 120.8(b)(2) and 9 CFR 417.2(c)(2), respectively), and critical limits (§§ 123.6(c)(3) and 120.8(b)(3) and 9 CFR 417.2(c)(3), respectively). The FSIS HACCP regulation for meat and poultry further requires that the written hazard analysis be maintained as part of the documentation for the establishment's HACCP plan (9 CFR 417.5(a)(1)). None of these documents recommends or requires that the HACCP plan include the procedures for analyzing the hazards or procedures for identifying the CCPs and critical limits. Rather, these documents are clear that it is the outcomes rather than the procedures for conducting the hazard analysis and identifying the preventive controls that are part of the plan.

4. Proposed § 117.126(c)—Preparation of the Food Safety Plan by a Qualified Individual

Proposed § 117.126(c) would require that the food safety plan be prepared by (or its preparation overseen by) a qualified individual. (See the discussion in section XII.H of this document regarding the qualifications of a qualified individual as would be established in proposed § 117.155(b)). Section 418 of the FD&C Act requires that firms identify and implement preventive controls and that facilities monitor and verify the effectiveness of the preventive controls. A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent illness or injury. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both.

Section 418 of the FD&C Act does not address the qualifications of the individual who would prepare the food safety plan. However, proposed § 117.126(c) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that, because of the technical nature required for the hazard analysis, experts who are knowledgeable in the food process either participate in or verify the hazard analysis and the HACCP plan (Ref. 34). Our HACCP regulations for seafood and juice require that the individual developing the HACCP plan complete training in the application of HACCP principles to juice or seafood processing under a standardized curriculum or be qualified through job experience that provides knowledge at least equivalent to that provided through the standardized curriculum (§§ 123.10 and 120.13, respectively). The FSIS HACCP regulation for meat and poultry requires that the individual developing the HACCP plan complete training in the application of HACCP principles to meat or poultry product processing (9 CFR 417.7).

One way to comply with proposed § 117.126(c) could be for a team of individuals (for example, a ''HACCP team'' or a ''food safety team'') to develop the food safety plan under the oversight of a qualified individual. Each member of a HACCP or food safety team generally brings specific expertise important in developing the plan. For example, a microbiologist could provide knowledge of microbial hazards, an engineer could establish the critical parameters for delivery of heat treatments, and a maintenance supervisor could identify sources of metal contamination. Proposed § 117.126 would not require that all such members of a food safety team satisfy the requirements in proposed

§ 117.126(c) for a qualified individual. However, under proposed § 117.126(c), a qualified individual must be responsible for ensuring that all components the food safety plan have been developed, including reviewing all information contained in the food safety plan, thereby verifying the hazard analysis and food safety plan developed by the food safety team.

5. Facility-Based Nature of the Written Food Safety Plan

The overall framework of section 418 of the FD&C Act is directed to a facility rather than, for example, a corporate entity that may have multiple facilities. For example, under section 418(b) of the FD&C Act the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards *that may be associated with the facility* (emphasis added). Thus, proposed § 117.126 establishes a requirement for every facility to have its own written food safety plan. The facility-based nature of the written food safety plan that would be required by proposed § 117.126 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines emphasize that it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan (Ref. 34). The Codex HACCP Annex states that HACCP should be applied to each specific operation separately (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require that HACCP plans be specific to each location where the product is processed (§§ 123.6(b)(1) and 120.8(a)(1) for seafood and juice, respectively) or to ''every official establishment'' (9 CFR 417.2(a)) for meat and poultry).

Federal HACCP regulations for seafood, juice, and meat and poultry allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical, provided that any required features of the plan that are unique to a specific product or production method are clearly delineated in the plan and are observed in practice (§§ 123.6(b)(2) and 120.8(a)(2) and 9 CFR 417.2(b)(2) for seafood, juice, and meat and poultry, respectively). This type of grouping would be allowed under proposed § 117.126 and, thus, would provide flexibility for facilities in the development of their HACCP plans.

B. Proposed § 117.130—Hazard Analysis

1. Requirements of Section 418 of the FD&C Act

Section 418(b)(1) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and (B) hazards that occur naturally, or may be unintentionally introduced. Section 418(b)(3) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall develop a written analysis of the hazards.

As discussed in section II.B.2.f of this document, this rulemaking is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism.'' Therefore, we are not implementing section 418(b)(2) of the FD&C Act in this proposed rule.

Section 418(c)(1) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(3) of the FD&C Act specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Sections 418(c)(1) and (c)(3) of the FD&C Act, which we will address more fully in section XII.C.1 of this document, are relevant to our discussion of proposed § 117.130(a) regarding the purpose of the hazard analysis required by section 418(b) of the FD&C Act.

2. Proposed § 117.130(a)—Hazard Analysis

a. Proposed § 117.130(a)(1)—Requirement to identify and evaluate hazards. Proposed § 117.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards, for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. As discussed more fully in the remainder of this section, proposed § 117.130(a)(1) would implement section 418(b)(1) of the FD&C Act.

Proposed § 117.130(a)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe a two-stage process for conducting a hazard analysis (Ref. 34), i.e., hazard identification and hazard evaluation. Hazard identification has been described as a brainstorming session designed to facilitate the development of a list of potential hazards, including those known to be associated with a type of food or process and those known to have occurred in a particular facility, for consideration during the hazard evaluation step (Ref. 143). Hazard evaluation is conducted after development of the list of potential hazards associated with each step in the product's process. The Codex HACCP Annex recommends that the HACCP team list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption and then conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (Ref. 35). Our HACCP regulation for juice requires that a hazard analysis both identify hazards and evaluate whether they are reasonably likely to occur (§ 120.7(a)(1) and (2)). Federal HACCP regulations for seafood and meat and poultry require that a processor or establishment conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur (§ 123.6(a) and 9 CFR 417.2(a)).

In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act describing the hazards that a facility would identify and evaluate—i.e., ''known or reasonably foreseeable hazards that may be associated with the facility.'' We consider that the ''known or reasonably foreseeable hazards'' in section 418(b) of the FD&C Act are analogous to the ''potential hazards'' discussed in the NACMCF HACCP guidelines, and the hazards that are required to be identified to determine if they are ''hazards that may be reasonably expected to occur at each step'' in the Codex HACCP Annex, or ''reasonably likely to occur'' in Federal HACCP regulations for seafood, juice, and meat and poultry.

Proposed § 117.130(a)(1) would establish the requirement to identify and evaluate hazards by conducting a hazard analysis; we propose specific requirements for the hazard identification in proposed § 117.130(b) (see section XII.B.3 of this document) and specific requirements for the hazard evaluation in proposed § 117.130(c) (see section XII.B.4 of this document).

Proposed § 117.130(a)(1) would require that the identification and evaluation of hazards be done ''for each type of food manufactured, processed, packed, or held at the facility.'' In considering the proposed requirement for a hazard analysis, we considered the language of section 418(b)(1) of the FD&C Act. The purpose of sections 418(b)(1) appears clear—i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the food produced by the facility. The known or reasonably foreseeable hazards associated with the facility's food may differ based on the type of food and, thus, the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry all apply a hazard analysis to each type of food manufactured, processed, packed, or held at the facility. Proposed § 117.130(a) would do likewise.

The NACMCF HACCP guidelines (Ref. 34) and Codex HACCP Annex (Ref. 35) describe several preliminary tasks that need to be accomplished before application of the HACCP principles to a specific product and process, including describing the food and its distribution, describing the intended use and consumers of the food, and developing a flow diagram for the process. Our HACCP regulations for seafood and juice require that the hazard analysis be conducted for each kind of fish or fishery product (or for each type of juice product) processed by the processor (§§ 123.6(a) and 120.7(a)) but do not mandate any particular process for the hazard analysis. The FSIS HACCP regulation for meat and poultry requires that a flow chart be prepared describing the steps for each process and product flow in the establishment (9 CFR 417.2(a)(2)) and also requires a HACCP plan for each product produced by the establishment whenever the hazard analysis reveals one or more hazards that are reasonably likely to occur (9 CFR 417.2(b)(1)).

The process of identifying and evaluating the hazards that may occur for specific types of food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of foods. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific foods when required. Thus, a facility may need to conduct multiple hazard analyses. For example, a facility that produces tea-based beverages may package its products in both glass and plastic bottles at the same facility. Although these two products might contain similar ingredients, we would consider them to be different types of food under proposed § 117.130(a)(1) because the two types of packaging entail significant differences in the handling of these products during processing. The hazard of glass particles resulting from glass container breakage during plant operations is a known hazard associated with glass-packaged products and, thus, should be identified and evaluated for the product packaged in glass but not for the product packaged in plastic.

Proposed § 117.130(a)(1) would identify the purpose of the hazard analysis—i.e., to determine whether there are hazards that are reasonably likely to occur. Although section 418(b)(1) of the FD&C Act does not explicitly identify the purpose of the hazard analysis, we interpret the combined requirements of sections 418(b), (c)(1) and (c)(3) of the FD&C Act to reflect a purpose, i.e., to enable the facility to identify and, where necessary, implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. If, for example, the facility concludes during the hazard analysis that one or more (or even all) known or reasonably foreseeable hazards are not reasonably likely to occur in the facility for a certain type of food, the facility could conclude that there is no need to identify and implement preventive controls for those hazards. The purpose of the hazard analysis identified in proposed § 117.130(a)(1) is consistent with the purpose identified in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines identify the purpose of the hazard analysis as the development of a list of hazards that are of such significance that they are reasonably likely to cause illness or injury if not effectively controlled (Ref. 34). The Codex HACCP Annex recommends that the HACCP team identify for the HACCP plan hazards that are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (Ref. 35). The stated purpose of the hazard analysis in Federal HACCP regulations for seafood, juice and meat and poultry is, in relevant part, to determine whether there are food safety hazards that are reasonably likely to occur for each kind of product (§§ 123.6(a) and 120.7(a), respectively, for seafood and juice) or in the production process for meat and poultry (9 CFR 417.2(a)).

b. Proposed § 117.130(a)(2)—Requirement for the hazard analysis to be written. Proposed § 117.130(a)(2) would require that the hazard analysis be written, as required by section 418(b)(3) of the FD&C Act. A written hazard analysis can help the facility organize the scientific basis for the hazard analysis and would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team needs to fully understand the nature of the hazards in order to produce a safe food. For example, although the facility's food safety plan would include corrective action procedures that address problems that can be anticipated, the food safety team will need to make decisions as to appropriate corrective actions when there is an unanticipated problem (see, e.g., the discussion of a proposed requirement (proposed § 117.145(b)) for corrective actions when there is an unanticipated problem in section XII.F.3 of this document). The written hazard analysis would be useful at these times. Having a written hazard analysis available for auditors and for inspectors is essential for them to assess the adequacy of the hazard analysis. A written hazard analysis also would be essential during reanalysis and updates of the hazard analysis, as would be required by proposed § 117.150(f) so that the person doing the reanalysis or update has a baseline from which to start. A written hazard analysis also would be useful for training purposes as a tool to make employees aware of food safety hazards that are reasonably likely to occur.

The written hazard analysis includes the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 117.130(a)(2) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely

to occur. Under proposed § 117.130(a)(2), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

Proposed § 117.130(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry. The NACMCF HACCP guidelines and the Codex HACCP Annex each specify that the hazard analysis be documented in the HACCP plan (Ref. 34) (Ref. 35). Our HACCP regulation for juice requires a written hazard analysis (§ 120.7(a)). Our HACCP regulation for seafood requires that the list of food safety hazards that are reasonably likely to occur, identified in the hazard analysis, be included in the written HACCP plan (§ 123.6(c)). The FSIS HACCP regulation for meat and poultry requires a written hazard analysis, including all supporting documentation (9 CFR 417.5(a)(1)).

3. Proposed § 117.130(b)—Hazard Identification

Proposed § 117.130(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance (proposed § 117.130(b)(1));
- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens (proposed § 117.130(b)(2));
- Physical hazards (proposed § 117.130(b)(3)); and
- Radiological hazards (proposed § 117.130(b)(4)).

Proposed § 117.130(b) would implement section 418(b)(1) of the FD&C Act and would establish four groups of hazards (i.e., biological, chemical, physical, and radiological). Three of the proposed groups of hazards (i.e., biological, chemical, and physical) are the same as the groups of hazards in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry; the proposed group ''radiological hazards'' would be in addition to the groups of hazards in those HACCP systems. The additional group of ''radiological hazards'' is required by section 418(b)(1)(A) of the FD&C Act. The NACMCF HACCP guidelines and Codex HACCP Annex identify biological, chemical, and physical hazards as types of hazards in the definition of hazard (Ref. 34) (Ref. 35). Federal HACCP regulations for seafood, juice and meat and poultry identify biological, chemical, and physical hazards as types of hazards in the definition of ''food safety hazard'' (§ 123.3(f) and 9 CFR § 417.1 for seafood and meat and poultry, respectively) or food hazard (§ 120.3(g) for juice). Federal HACCP regulations for seafood, juice, and meat and poultry identify as hazards microbiological contamination, parasites, chemical contamination, unlawful pesticide residues, decomposition, natural toxins, unapproved use of food or color additives and physical hazards (§§ 123.6(c)(1), 120.7(c), and 9 CFR 417.2(a)(3), respectively). Federal HACCP regulations for seafood and meat and poultry also identify as hazards drug residues (§ 123.6(c)(1)(v) and 9 CFR 417.2(a)(3)(v) for seafood and meat and poultry, respectively) and undeclared ingredients that may be allergens (§ 120.7(c)(8) for juice). The FSIS HACCP regulation for meat and poultry also identifies zoonotic diseases as a hazard (9 CFR 417.2(a)(3)).

Microbiological Hazards

Proposed § 117.130(b)(1) would include microbiological hazards within the category of biological hazards. Examples of microbiological hazards include:

- Parasites (which are required to be considered by section 418(b)(1)(A) of the FD&C Act). A parasite is an organism that lives on or in an organism of another species (often called the host organism) and feeds off that other species. *Cryptosporidium* spp., *Giardia intestinalis,* and *Toxoplasma gondii* are examples of parasites.
- Environmental pathogens (e.g., *Listeria monocytogenes* and *Salmonella* spp.); and
- Other microorganisms of public health significance, including bacteria (e.g., *Campylobacter* spp., *Clostridium perfringens,* Shiga toxin-producing *Escherichia coli* (STEC) O157, STEC non-O157, *Shigella* spp., *Staphylococcus aureus, Vibrio* spp., and *Yersinia enterocolitica*) and viruses (e.g., hepatitis A virus and norovirus).

As discussed in section II.D.1 of this document, CDC has estimated that the total burden of foodborne illness is 48 million cases, 128,000 hospitalizations, and 3,000 deaths due to illnesses from both major pathogens and from unspecified agents (Ref. 45) (Ref. 46). Focusing only on the foodborne illnesses attributable to particular pathogens, a recent report estimated that 31 major pathogens (for which data for preparing national estimates are available, including those listed above) cause 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1351 deaths in the United States each year (Ref. 45). In addition to contaminating raw materials, some of these pathogens (e.g., *Listeria monocytogenes* and *Salmonella* spp.) are common pathogens of concern with respect to contamination from the processing environment for specific types of facilities (Ref. 144) (Ref. 145). (See sections I.D and I.E of the Appendix to this document for a discussion of testing programs for environmental pathogens). Contamination of food with some pathogens (e.g., *Staphylococcus aureus* and norovius) is often due to poor employee hygiene or practices.

Chemical Hazards

Proposed § 117.130(b)(2) would include substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens (all of which are required to be considered by section 418(b)(1)(A) of the FD&C Act) within the category of chemical hazards. As discussed in section II.D.2.b of this document, pesticide residues may be present in food in the absence of or in excess of a tolerance established by EPA. Residues of drugs (e.g., antibiotics administered to dairy cows) may be present in food derived from the animal (such as milk) in the absence of or in excess of a tolerance or safe levels established and enforced by FDA (Ref. 146). Natural toxins such as aflatoxin and patulin are well recognized as hazards in foods such as peanuts and apple juice products, respectively (Ref. 82) (Ref. 85). Decomposition products such as histamine, produced from the amino acid histidine when certain bacteria grow, can pose a risk to health. An undeclared food allergen (such as a peanut) can cause a life-threatening reaction (such as anaphylactic shock) in susceptible individuals (Ref. 147). Heavy metals (such as lead) can lead to impaired cognitive development in children (Ref. 88).

Physical Hazards

Proposed § 117.130(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include stones, glass, or metal fragments that could inadvertently be introduced into food. Physical hazards may be associated with raw materials, especially RACs. The facility and equipment can also be a source of

physical hazards, e.g., container glass and metal fragments such as nuts and bolts.

Radiological Hazards

Proposed § 117.130(b)(4) would require that the hazard analysis consider radiological hazards. As discussed in section II.D.2.e of this document, examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium-235, uranium-238, strontium-90, iodine-131, and cesium-137. The NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry do not identify radiological hazards as a type of hazard to be considered in the hazard analysis. However, section 418(b)(1)(A) of the FD&C Act requires that radiological hazards be considered, and food may be subject to contamination with radiological hazards—e.g., if water used to manufacture a food contains a radionuclide. For additional information on how radiological hazards may contaminate food, see section III.D.2.e of this document and references discussed therein (Ref. 107) (Ref. 108) (Ref. 109).

4. Proposed § 117.130(c)—Hazard Evaluation

a. Proposed § 117.130(c)(1)—Evaluation of whether a hazard is reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. Proposed § 117.130(c)(1) would require that the hazard analysis include an evaluation of the hazards identified in § 117.130(b) to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. As discussed in more detail later in this section, proposed § 117.130(c)(1) would implement sections 418(b)(1) and (c)(3) of the FD&C Act. Proposed § 117.130(c)(1) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines define severity as the seriousness of the effects of a hazard. The severity of the illness or injury includes the magnitude and duration of the illness and impact of any sequelae (chronic conditions resulting from an illness, such as reactive arthritis following a *Salmonella* infection). The NACMCF HACCP guidelines also recommend considering the likelihood of an illness or injury (usually based upon a combination of experience, epidemiological data, and information in the technical literature) and the potential effects associated with both short-term and long-term exposure (Ref. 34). Likewise, the Codex HACCP Annex recommends that the hazard analysis consider the severity of the adverse health effects associated with the hazards (Ref. 35). Our juice HACCP regulation requires that the hazard evaluation include an assessment of the severity of the illness or injury if the hazard occurs (§ 120.7(a)(2)). The requirement for a hazard analysis in our seafood HACCP regulation does not specifically require an assessment of severity but addresses the potential for illness or injury in its definition of a food safety hazard, which refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (§ 123.3(f)) and in the description of a food safety hazard that is reasonably likely to occur, which includes illness data as a basis for establishing controls (§ 123.6(a)). Similarly, the FSIS HACCP regulation for meat and poultry does not specifically require an assessment of severity in the hazard analysis (9 CFR 417.2(a)), but its definition of a food safety hazard refers to biological, chemical or physical properties that may cause a food to be unsafe for human consumption (9 CFR 417.1(c)). In the final rule to establish our juice HACCP regulation, we agreed with the NACMCF approach to conducting the hazard analysis—i.e., that the process of evaluating food hazards to determine which potential hazards need to be addressed in the HACCP plan (i.e., those that are reasonably likely to occur) takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (66 FR 6138 at 6155).

As discussed in section II.D.2.a of this document, contamination of food with biological hazards often leads to immediate or near-term onset of illness or injury (e.g., gastrointestinal illness). Exposure to some biological hazards may have long-term consequences as well (e.g., infections with *Salmonella* spp. may result in reactive arthritis). The effects of exposure to some biological hazards are severe (e.g., Hemolytic Uremic Syndrome (HUS) in individuals exposed to *E. coli* O157:H7 (63 FR 20450 at 20450) or invasive listeriosis in susceptible individuals exposed to *L. monocytogenes* in ready-to-eat foods (Ref. 55). Proposed § 117.130(c)(1) would require that such biological hazards be considered to determine whether they are reasonably likely to occur even if the biological hazard occurs infrequently.

As discussed in sections II.D.2.b and II.D.2.c of this document, contamination of food with chemical hazards may lead to immediate or near-term onset of illness—e.g., an allergic reaction to an undeclared peanut or to a residue in a milk product of penicillin used to treat the cow. In other instances the focus of the evaluation for chemical hazards is directed to their long term effects, such as impaired cognitive development in children exposed to lead in contaminated candy (Ref. 88) and liver cancer as the result of chronic exposure to the mycotoxin aflatoxin (Ref. 89) (Ref. 90). Proposed § 117.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

We discuss the regulatory framework under the FD&C Act (including premarket approval or registration by FDA or EPA) of food additives, color additives, new animal drugs, and pesticides in section II.D.2.b of this document. An additive, drug, or pesticide that has been approved for use in some foods, but not other foods, is deemed by the FD&C Act to be unsafe for use with those other foods. Proposed § 117.130(c)(1) would require that chemical hazards such as unapproved food additives, unapproved color additives, new animal drugs, and pesticides be considered to determine whether they are reasonably likely to occur.

We provide information about natural toxins (such as aflatoxin and patulin), decomposition products (such as histamine and other biogenic amines), and heavy metals (such as lead) in section II.D.2.b of this document and references contained therein (Ref. 82) (Ref. 83) (Ref. 84) (Ref. 85) (Ref. 86) (Ref. 87) (Ref. 88) (Ref. 90). Proposed § 117.130(c)(1) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Physical hazards such as hard and sharp foreign objects that may be present in food can pose a health risk (Ref. 148). Hard or sharp foreign objects in food may cause traumatic injury, including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums (Ref. 148) (Ref. 149). Thus, even if physical hazards occur infrequently, under proposed § 117.130(c)(1) the potential for severe consequences would require consideration of these physical hazards to determine whether they are

reasonably likely to occur. Factors relevant to an evaluation of the severity of a physical hazard include the potential size of the object, the nature of the food (e.g., RTE or required to undergo further processing), and whether intended consumers of the food include special risk groups (Ref. 148).

Contamination of food with radiological hazards generally is evaluated for long-term effects such as the potential for cancer (Ref. 150). A significant radiation dose could be received as a result of consumption of food contaminated as a result of an accident at a nuclear power plant or other types of accidents (Ref. 150; see also (63 FR 43402, August 13, 1998)). Foods may contain unsafe levels of radionuclides (Ref. 151). Thus, although radiological hazards occur infrequently, under proposed § 117.130(c)(1) the potential for severe consequences would require consideration of radiological hazards to determine whether they are reasonably likely to occur for a particular food or facility, especially when circumstances arise that could lead to contamination of food with radiological hazards.

The purpose of sections 418(b)(1) and 418(c)(3) of the FD&C Act seems clear—i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for the purpose of identifying and implementing preventive controls to provide assurances that identified hazards will be significantly minimized or prevented and that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. The process of evaluating food hazards to determine which potential hazards require preventive controls must take into account the consequences of exposure (i.e., severity) as well as the probability of occurrence (i.e., frequency) to provide assurances that the food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Proposed § 117.130(c)(1) would implement this statutory direction.

b. Proposed § 117.130(c)(2)—Requirement to evaluate environmental pathogens. Proposed § 117.130(c)(2) would require that the hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever an RTE food is exposed to the environment prior to packaging. As noted in section II.D.2.a of this document, environmental pathogens can be a source of contamination of food. Examples of environmental pathogens that have contaminated foods (and, in particular, RTE foods) include *Salmonella* spp. and *L. monocytogenes.* Proposed § 117.130(b)(1) would include environmental pathogens as one of the biological hazards that must be considered in identifying hazards for evaluation. Under proposed § 117.130(c)(2), a facility that produces an RTE food that is exposed to the environment would be required to identify *environmental pathogens* as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility.

c. Proposed § 117.130(c)(3)—Consideration of specific factors relevant to the hazard evaluation. Proposed § 117.130(c)(3) would require that, in conducting the hazard evaluation, consideration be given to the effect of several specific factors on the safety of the finished food for the intended consumer. We tentatively conclude that these are factors that a prudent person who manufactures, processes, packs, or holds foods would consider when evaluating identified hazards to determine whether they are reasonably likely to occur. As we indicated in proposing our HACCP regulation for juice, a prudent processor should consider factors such as these in doing a hazard analysis (63 FR 20450 at 20468).

Proposed § 117.130(c)(3)(i) would require that the hazard evaluation consider the formulation of the food. The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, since they may inhibit growth of, or even kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of ''pathogen growth.'' A multi-component food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w), but when put together there may be an interface where the pH and a_w changes (e.g., pies, layered breads). Under proposed § 117.130(c)(3)(i), the interaction of the individual ingredients must be evaluated as part of the formulation of the food. Proposed § 117.130(c)(3)(i) also would require that the hazard evaluation consider whether or not the formulation contains an ingredient (such as a flavoring, coloring, or incidental additive) that may contain an allergen.

Proposed § 117.130(c)(3)(ii) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment. The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., with close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments. Proposed § 117.130(c)(3)(ii) would require that facilities with such equipment consider the impact of the equipment on the potential for pathogens to be a hazard that is reasonably likely to occur; if so, a preventive control such as enhanced sanitation controls may be appropriate, particularly if the equipment is used in production of RTE food. Equipment designed such that there is metal-to-metal contact may generate metal fragments. Proposed § 117.130(c)(3)(ii) would require that facilities with such equipment consider the impact of the equipment on the potential for generation of such metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs soft, fresh cheese (such as queso fresco, which is consumed without cooking to adequately reduce pathogens) may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate food-contact surfaces and, eventually, foods. Proposed § 117.130(c)(3)(ii) would require that facilities with such conditions consider the impact of the conditions on the potential for whether development of a niche where the pathogen *L. monocytogenes* can become established is a hazard that is reasonably likely to occur; if so, enhanced sanitation controls may be appropriate. A facility design that has closely spaced equipment would provide more opportunities for cross-contact (such as from allergens in powdered milk or soy) from one line to another (e.g., through dust) than a facility that has more spacing between equipment. Proposed § 117.130(c)(3)(ii) would require that facilities with such closely spaced equipment consider the impact of the close spacing on the potential for cross-contact to be a hazard

that is reasonably likely to occur; if so, targeted food allergen controls may be appropriate.

Proposed § 117.130(c)(3)(iii) would require that the hazard evaluation consider raw materials and ingredients. Current § 110.3 defines ''food'' to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients, and that definition would be retained (with no proposed revisions) in this proposed rule. As discussed in section IX.E of this document, there is an overlap between raw materials and ingredients; not all raw materials are ingredients. A food can become contaminated through the use of contaminated food ingredients. For example, in the past several years thousands of foods have been recalled as a result of contamination of food ingredients with pathogens such as *Salmonella* spp. and *E. coli* O157:H7. The ingredients included peanut-derived ingredients (Ref. 19) (Ref. 20), pistachio-derived ingredients (Ref. 152), hydrolyzed vegetable protein (Ref. 23) (Ref. 24) (Ref. 153)), instant nonfat dried milk, whey protein, and fruit stabilizers (Ref. 21) (Ref. 22), and bagged spinach (Ref. 154). In some cases, the contamination was discovered only after the ingredient was associated with an outbreak of foodborne illness (Ref. 19). In other cases, the contamination was discovered in a food and associated with a particular ingredient without any known incidence of foodborne illness (Ref. 152) (Ref. 155) (Ref. 22) (Ref. 154). Following some of these recalls, we issued guidance recommending that manufacturers of foods containing a particular type of ingredient either obtain the ingredients from suppliers with validated processes in place to adequately reduce the presence of the applicable pathogen, or ensure that their own manufacturing process would adequately reduce the presence of that pathogen (Ref. 6) (Ref. 156). Specific pathogens would be considered to be a hazard that is reasonably likely to occur for raw materials and ingredients that have been documented to be contaminated with such pathogens, as well as for ingredients with similar characteristics (because such contamination might be expected in ingredients that are produced in a similar manner).

A food also may become contaminated through the use of contaminated raw materials that are not food ingredients. In the example of the manufacture of the food additive sucrose fatty acid esters (see discussion in section IX.E of this document), § 172.859 establishes specifications for sucrose fatty acid esters, such as specifications that arsenic is not more than 3 parts per million, total heavy metal content (as lead) is not more than 50 parts per million, and lead is not more than 10 parts per million (§ 172.859(b)(6), (7), and (8)). The use of raw materials that are contaminated with arsenic, lead, or other heavy metals that would not be removed as part of the manufacturing process for sucrose fatty acid esters could lead to sucrose fatty acid esters that are contaminated with arsenic, lead, or other heavy metals such that they do not satisfy the specifications of the regulation.

As noted for formulation in the discussion of proposed § 117.130(c)(3)(i), ingredients must be evaluated for ''hidden'' allergens such as may be present in flavorings, colorings, or incidental additives. Production and harvesting practices may impact whether raw materials and ingredients contain hazards. For example, machinery-harvested produce is more likely to be contaminated with physical hazards than hand-picked produce, because the machinery often picks up foreign material from the field.

Proposed § 117.130(c)(3)(iv) would require that the hazard evaluation consider transportation practices. A food may become unsafe as a result of poor transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, failure to adequately control temperature during transportation could make a food unsafe if the product requires time and temperature controls to ensure safety. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation—e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination (Ref. 157). (For additional examples of food safety problems that could occur during transportation, see 75 FR 22713, April 30, 2010).

The Sanitary Food Transportation Act of 2005 (SFTA) gives FDA authority to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. In 2010, we published an Advance Notice of Proposed Rulemaking to request data and information on the food transportation industry and its practices and we expect to issue a separate proposed rule to implement the SFTA (75 FR 22713, April 30, 2010). We do not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur.

Proposed § 117.130(c)(3)(v) would require that the hazard evaluation consider manufacturing/processing procedures. For example, hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic sporeforming bacteria such as *Clostridium perfringens* and *Bacillus cereus* (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of *C. botulinum,* with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria *Staphylococcus aureus* or *Bacillus cereus* in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and *S. aureus* or *B. cereus* is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., *S. aureus*). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.

Proposed § 117.130(c)(3)(vi) would require that the hazard evaluation consider packaging activities and labeling activities. For example, as discussed earlier in this section XII.4.c the hazards that are reasonably likely to occur would be different depending on whether a product is packaged in glass bottles or in plastic bottles. A label on a food may direct consumers to cook a product to a certain temperature; the likelihood of consumers following those cooking instructions may vary depending on the type of food. For example, it is well known that consumers will eat raw cookie dough, even though the cookie dough is clearly intended to be cooked, and an outbreak of foodborne illness has been associated with the consumption of uncooked cookie dough (Ref. 77) (Ref. 76) (Ref. 78). Thus, although label information is a factor to consider, a hazard may be reasonably likely to occur even with

label information such as cooking instructions.

Proposed § 117.130(c)(3)(vii) would require that the hazard evaluation consider storage and distribution. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled.

Proposed § 117.130(c)(3)(viii) would require that the hazard evaluation consider intended or reasonably foreseeable use. An example of intended or reasonably foreseeable use is whether the food would be cooked by the consumer. In some cases, the intended use of a product may include uses where it would be cooked by the consumer, as well uses where it would not be cooked. For example, soup is generally cooked, but a dried soup mix is often used in RTE form as a component of a dip. For another example, see the discussion of consumption of raw cookie dough earlier in this section. When it is known or reasonably foreseeable that a food would be consumed in RTE form, hazards such as *Salmonella* spp., *L. monocytogenes,* and *E. coli* O157:H7 would need to be considered to determine if they are hazards reasonably likely to occur.

Proposed § 117.130(c)(3)(ix) would require that the hazard evaluation consider sanitation, including employee hygiene. Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella* spp., hepatitis A and norovirus.

Proposed § 117.130(c)(3)(x) would require that the hazard evaluation consider any other relevant factors that might potentially affect the safety of the finished food for the intended consumer. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be a hazard reasonably likely to occur. As another example, when local water authorities advise the public to boil tap water for drinking, a facility should consider whether bacterial, viral or parasitic (e.g., *Cryptosporidium* and *Giardia*) contamination presents a hazard reasonably likely to occur as a result of the events that triggered the advisory (Ref. 158).

Proposed § 117.130(c)(3) is consistent with the NACMCF HACCP guidelines, the Hazards and Controls Guides we have issued regarding our HACCP regulations for juice and seafood, and the Hazards and Controls Guide FSIS has issued regarding the FSIS HACCP regulation for meat and poultry. The NACMCF HACCP guidelines note that hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product—e.g., due to differences in equipment and/or maintenance programs (Ref. 34). Appendix C of the NACMCF HACCP guidelines provides examples of questions to be considered when conducting a hazard analysis and identifies factors to consider such as ingredients, formulation, processing procedures, design of facility, design and use of equipment, packaging, sanitation, worker health and hygiene, storage, intended use, and intended consumer. Our Hazards and Controls Guide for juice provides recommendations related to factors such as shelf life of the product, location of the processing, and type of processing, e.g., thermal or non-thermal processing (Ref. 4). Our Hazards and Controls Guide for seafood provides recommendations related to factors such as storage conditions (time and temperature), the role of manufacturing conditions in minimizing the potential for formation of *C. botulinum* toxin, manufacturing procedures (cooking and pasteurization) to control pathogenic bacteria, manufacturing procedures (such as high hydrostatic pressure processing, individual quick freezing with extended frozen storage, mild heat processing, and irradiation) designed to retain raw product characteristics, and the introduction of pathogenic bacteria after pasteurization and specialized cooking processes. The FSIS Hazards and Controls Guide for meat and poultry provides recommendations related to factors such as receiving, thawing, formulation, manufacturing procedures, packaging, storage and shipping (Ref. 159).

C. Proposed § 117.135—Preventive Controls for Hazards That Are Reasonably Likely To Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c)(1) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(1)(3) of the FD&C Act), in relevant part, specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

As discussed in section X.B.4 of this document, section 418(o)(3) of the FD&C Act defines preventive controls and proposed § 117.3 would include the statutory definition in proposed part 117. Under section 418(o)(3), the procedures, practices, and processes described in the definition of preventive controls may include the following:

- Sanitation procedures for food-contact surfaces and utensils and food-contact surfaces of equipment (section 418(o)(3)(A) of the FD&C Act);
- Supervisor, manager, and employee hygiene training (section 418(o)(3)(B) of the FD&C Act);
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment (section 418(o)(3)(C) of the FD&C Act);
- A food allergen control program (section 418(o)(3)(D) of the FD&C Act);
- A recall plan (section 418(o)(3)(E) of the FD&C Act);
- CGMPs under part 110 or any successor regulations (section 418(o)(3)(F) of the FD&C Act); and
- Supplier verification activities that relate to the safety of food (section 418(o)(3)(G) of the FD&C Act).

2. Proposed § 117.135(a)—Requirement To Identify and Implement Preventive Controls for Hazards that Are Reasonably Likely To Occur

Proposed § 117.135(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed or held by such

facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

As discussed in section XII.B.2.a of this document, proposed § 117.130(a) would require that the owner, operator, or agent in charge of a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are ''reasonably likely to occur.'' Under proposed § 117.135(a), a facility that determines through its hazard analysis that there are hazards that are reasonably likely to occur would then be required to identify and implement preventive controls for those hazards. Preventive controls would be required when applicable hazards are identified as reasonably likely to occur. As discussed in sections XII.B.2 through XII.C.10 of this document, the types of preventive controls implemented would depend on the facility and the food it produces. Most hazards would be addressed through process controls, food allergen controls, and sanitation controls. For any type of preventive control, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 117.135(a).

Proposed § 117.135(a) would implement section 418(c) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry, although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood, juice, and meat and poultry (§§ 123.6 and § 120.7 and 9 CFR 417.2, respectively) direct a processor to address potential hazards that are reasonably likely to cause illness or injury in the absence of their control by determining CCPs and establishing critical limits for those CCPs. As discussed in section II.C.2 of this document, although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls. Under proposed § 117.135(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its food allergen control program, which may not have specific CCPs. (For discussion of the food allergen control program that would be required by proposed § 117.135(d)(2), see section XII.C.6 of this document.)

Whatever types of preventive controls a facility chooses to apply in its operations, the requirement in proposed § 117.135(a) would be risk based. Establishing risk-based preventive controls involves consideration of the available scientific data and information related to food safety risks. Typically, the hazard evaluation will enable the facility to determine appropriate risk-based preventive controls for the hazard based on the severity of the hazard and the likelihood of its occurrence.

For example, as discussed in section I.D.6 of the Appendix to this document, *L. monocytogenes* is an environmental pathogen that can establish a harborage in the environment such as on a production line used in wet manufacturing. Once established, *L. monocytogenes* can intermittently contaminate products on the production line. When a hazard analysis identifies *L. monocytogenes* as a hazard that is reasonably likely to occur in a food, the facility would establish sanitation controls to prevent *L. monocytogenes* from establishing itself in a harborage site. In addition to such sanitation controls, a facility may consider applying a listericidal process step (i.e., a process control applied to adequately reduce levels of *L. monocytogenes* in RTE foods). As discussed in section II.D.2.a of this document, some RTE foods (like soft cheese) support the growth of *L. monocytogenes,* while others (like hard cheese) do not. The FAO/WHO *Listeria* risk assessment demonstrated that the risk of serious illness from consumption of RTE products contaminated with *L. monocytogenes* increases with the number of *L. monocytogenes* in an RTE food (Ref. 160). Thus, as a risk-based approach to the control of the biological hazard *L. monocytogenes,* the facility may elect to apply a listericidal process step to those RTE foods that support growth of *L. monocytogenes* in addition to its sanitation controls, but not apply such a process to those RTE foods that do not support growth of *L. monocytogenes.*

3. Proposed § 117.135(b)—Requirement for Written Preventive Controls

Proposed § 117.135(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. Proposed § 117.135(b) would implement section 418(h) of the FD&C Act which, as discussed in section XII.A.2 of this document, requires that the owner, operator, or agent in charge of a facility prepare a written food safety plan that, among other things, identifies the preventive controls within the plan. Written preventive controls are essential for the facility to implement the preventive controls consistently and essential for the facility's food safety team, auditors, and inspectors. Written preventive controls also would be essential for training purposes and during reanalysis and updates of the preventive controls. Proposed § 117.135(b) is consistent with our HACCP regulation for juice, which requires that the written hazard analysis identify control measures that the processor can apply to control the food hazards identified as reasonably likely to occur (§ 120.7(a)).

4. Proposed § 117.135(c)—Requirement for Parameters Associated With the Control of Hazards That Are Reasonably Likely To Occur

Proposed § 117.135(c)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, dehydrating, and refrigerating foods. Proposed § 117.135(c)(1) would include examples of several measures identified in current § 110.80(b)(4) (Manufacturing Operations) (proposed § 117.80(c)(4)) that if used as a preventive control must be adequate when used to prevent adulteration, but would not establish an exhaustive list of such processes, just as current § 110.80(b)(4) (proposed § 117.80(c)(4)) does not establish an exhaustive list of measures that must be adequate. Examples of other processes that would require the identification of parameters if used as a preventive control are brining, chilling, high pressure processing, treating with ultraviolet light, and washing with antimicrobial agents. The parameters are those factors that must be controlled to ensure the hazard will be significantly minimized or prevented. The specific parameters required, and how they would be controlled, would depend on

the facility and the food. For example, for a heat process, parameters such as temperature and time must be controlled. Temperature may be controlled through controls on product temperature (as when treating a fluid product in a heat exchanger) or through controls on oven temperature (as when heating product in an oven). Foods such as beverages lend themselves to a heat exchanger; foods such as baked goods lend themselves to an oven. Heating time may be controlled automatically by a pump setting that controls flow of the fluid through the heat exchanger and hold tube or manually by an operator recording the time a product is put in the oven and the time it is removed. Heating time may also be controlled by the belt speed for the conveyor on a continuous oven. A facility would have flexibility to establish controls on heating time through these or other mechanisms.

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters. Similarly, label controls for food allergens do not involve identification of specific parameters.

Proposed § 117.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any biological, chemical, radiological, or physical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Some of the preventive controls a facility may implement may be based upon scientific studies or other information that demonstrate the effectiveness of the control measure at specific values of a physical, biological, radiological or chemical parameter, e.g., the application of heat to food at a specific time/temperature combination to adequately reduce pathogens. Proposed § 117.135(c)(2) would require that a facility that establishes such a preventive control specify values of the essential parameters to be applied in implementing the control. Specifying these values would enable the facility to implement them consistently, would facilitate validation of the preventive controls as would be required by proposed § 117.150(a), and would facilitate audits and inspection.

Proposed § 117.135(c)(1) and (2) would implement section 418(c) of the FD&C Act and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry, although there are some differences related to the differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. The NACMCF HACCP guidelines and the Codex HACCP Annex (Ref. 34) (Ref. 35) each specify that the critical limits be documented in the HACCP plan. Federal HACCP regulations for seafood, juice, and meat and poultry each require that HACCP plan list the critical limits that must be met at each of the CCPs (§§ 123.6(c)(3) and 120.8(b)(3), and 9 CFR 417.2(c)(3), respectively). The NACMCF HACCP guidelines define ''critical limit'' to mean a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The definition of ''critical limit'' in Federal HACCP regulations for seafood, juice, and meat and poultry are, for practical purposes, identical to the definition in the NACMCF HACCP guidelines (§§ 123.3(c) and 120.3(e) and 9 CFR 417.1(b), respectively). The Codex HACCP Annex defines ''critical limit'' to mean a criterion which separates acceptability from unacceptability (Ref. 35).

FSMA does not use the term ''critical limit.'' As discussed in section II.C.2 of this document, although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls. Critical limits may not be appropriate for preventive controls that are not applied at CCPs. Thus, proposed § 117.135(c)(1) and (2) use a broader term—i.e., parameter—to encompass preventive controls that may or may not apply at CCPs. Consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry, proposed § 117.135(c)(2) would require the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. This is similar to requiring critical limits at CCPs but would apply to values set for parameters that apply to preventive controls, whether these apply at a CCP or not.

5. Proposed § 117.135(d)(1)—Process Controls

Proposed § 117.135(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls do not include those procedures, practices, and processes that are not applied to the food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards that are reasonably likely to occur but are not applied to the food itself. Specifying that process controls are employed during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur would distinguish those controls applied in manufacturing/processing that significantly minimize or prevent hazards (e.g., cooking, cooling, irradiating, refrigerating, and reducing water activity) from other types of controls that may be applied in manufacturing/processing to provide the desired product (e.g., controls for product size and shape). Many process controls, such as the application of heat to a food to adequately reduce pathogens, are applied in the same manner and for the same purpose as control measures established within HACCP plans and applied at CCPs as recommended by the NACMCF HACCP guidelines (Ref. 34) and the Codex HACCP Annex (Ref. 35) and as required by Federal regulations for seafood, juice, and meat and poultry (§§ 123.6(c)(3) and 120.8(b)(3)) and 9 CFR 417.2(c)(3), respectively).

As discussed in section XII.C.4 of this document, proposed § 117.135(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, when applicable, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled. For process controls in particular, the term ''parameter'' used in proposed § 117.135(c)(1), and the value associated with the parameter in proposed § 117.135(c)(2), are associated with the term ''critical limit'' used in HACCP systems. We described the use of the

term ''critical limit'' in other contexts in the previous section of this document. Collectively, proposed § 117.135(b), (c) and (d)(1) would require that a facility include in its written process controls information equivalent to that provided when listing critical limits that must be met at each of the CCPs, such as is required in our HACCP regulations for seafood and juice (§§ 123.6(c)(3) and 120.8((b)(3), respectively). However, the process controls may or may not apply at CCPs.

For example, a facility that holds in-shell pistachios in bulk storage units for an extended time period until they are shelled and packaged may identify the potential for growth of aflatoxin-producing molds on the nuts as a hazard reasonably likely to occur. As a process control to prevent such molds from growing on the nuts during storage, the facility may elect to dry (dehydrate) the nuts to a specific moisture content (e.g., no more than seven percent) prior to placing them in storage. The process control would be ''drying'' and the associated parameter would be moisture level, with its maximum value, or limit, being seven percent.

As another example, a facility that manufactures refrigerated deli salads may identify the potential for growth of *L, monocytogenes* in the salads as a hazard reasonably likely to occur. As a process control to prevent such growth, the facility may elect to add an acidifying agent during its process to ensure that the pH of the product does not exceed 4.4. The process control would be ''acidifying'' and the associated parameter would be pH, with its maximum value, or limit, being 4.4.

A facility that manufactures a deli salad product may establish refrigeration as a process control to prevent growth of pathogenic sporeformers such as *B. cereus,* if it determines this organism is a hazard reasonably likely to occur in the deli salads being produced. (A facility may conclude that refrigeration is not necessary to prevent the growth of pathogenic sporeformers if, for example, it controls this potential hazard through product formulation, such as pH.) The facility may also establish process controls addressing the amount of time that in-process materials are held above 4 °C (40 °F) during manufacturing and addressing their temperatures during this time period. If so, the process control would be ''manufacturing time'' and the associated parameters would be time and temperature, with the maximum time that in-process materials are held above 4 °C (40 °F) being specified.

6. Proposed § 117.135(d)(2)—Food Allergen Controls

Proposed § 117.135(d)(2)(i) would require that food allergen controls include those procedures, processes, and practices employed for ensuring protection of food from cross-contact, including during storage and use. Examples of such controls include procedures for separating ingredients and finished products that contain allergens from those that do not contain allergens, and procedures for separating foods that contain different allergens. Such controls are essential to prevent the inadvertent incorporation of an allergen into a product for which it is not an ingredient. Examples of such procedures for controlling food allergens include procedures that:

- Provide physical barriers;
- Eliminate or minimize the formation of dust, aerosols, or splashes;
- Conduct manufacturing/processing of foods in different parts of a facility;
- Emphasize separation in time, such as by production sequencing or by cleaning equipment between production runs;
- Emphasize storage and handling appropriate to reduce the potential for cross-contact; and
- Control the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods that do not, or when the same production lines are used for foods that contain different allergens.

Proposed § 117.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the act. Such controls can prevent application of the wrong label to a food, use of the wrong packaging, and use of packaging with an incorrect allergen declaration. Examples of such procedures for controlling food allergens include procedures that:

- Ensure that the food label correctly declares all of the food allergens present (including those contained in flavorings, colorings, and incidental additives);
- Ensure that the correct food label is applied to a food;
- Ensure that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food); and
- Review formulations and compare them to the labels (especially when new batches of labels are received).

Proposed § 117.135(d)(2) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3) of the FD&C Act. Proposed § 117.135(d)(2) is consistent with our HACCP regulation for juice, which requires processors to consider whether the presence of undeclared ingredients that may be allergens is a hazard that is reasonably likely to occur (§ 120.7(c)(8)). Proposed § 117.135(d)(2) also is consistent with the recommendations in the CGMP Working Group Report (Ref. 1) that food processing establishments that produce foods containing a major food allergen be required to have a food allergen control plan that addresses segregation of food allergens during storage and handling, prevention of cross-contact during processing, product label review, and label usage and control.

7. Proposed § 117.135(d)(3)—Sanitation Controls

Proposed § 117.135(d)(3)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard). Proposed § 117.135(d)(3)(i)(A) would require that sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging and any food allergen hazard. (We would generally not expect that microorganisms of public health significance contaminating an RTE food due to employee handling would be a hazard relevant to procedures for cleaning food-contact surfaces.) Examples of sanitation controls related to the cleanliness of food-contact surfaces include cleaning and sanitizing procedures (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time). Such controls can prevent contamination of food with microorganisms of public health significance, including environmental pathogens, that result from inadequate cleaning of food-contact surfaces. Such controls also can prevent cross-contact that results from inadequate cleaning of food-contact

surfaces or surfaces that transfer material to food-contact surfaces.

Proposed § 117.135(d)(3)(i)(B) would require that sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. Such hazards would include any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to contaminate food if employees are handling RTE food, and any food allergen hazard. Examples of sanitation controls to prevent cross-contact include procedures for ensuring that production utensils and maintenance tools do not transfer an allergen from one product to another (e.g., by proper cleaning of utensils and maintenance tools between uses if it is not practical to dedicate utensils and tools to specific processing lines); procedures for ensuring that personnel practices do not result in transfer of allergens from one production line to another (e.g., by ensuring employees do not handle food containing an allergen and one that does not without washing hands and changing outer garments); and procedures for minimizing the transfer of dust containing allergens (e.g., by cleaning powder spills around dumping stations as they occur).

Examples of sanitation controls to prevent cross-contamination include procedures for ensuring that personnel do not touch insanitary objects (e.g., waste, trash cans, the floor, and rest room fixtures or surfaces) and then food, food-contact surfaces, or food packaging material without first washing and sanitizing their hands; procedures for protecting food packaging material from environmental contamination; procedures for protecting exposed food products from contamination from the environment; and procedures for controlling traffic (including traffic of people and traffic of equipment such as forklifts) between the raw and finished sides of the operation.

To make clear that sanitation controls are required when an environmental pathogen is a hazard that is reasonably likely to occur in an RTE food that is exposed to the environment prior to packaging, proposed § 117.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. Recent outbreaks of foodborne illness caused by environmental pathogens (e.g., *Salmonella* spp. and *L. monocytogenes*), as well as the scientific literature, emphasize the critical need for sanitation controls to minimize the potential for food, particularly RTE food, to become contaminated with environmental pathogens. (See sections I.D and I.E of the Appendix to this document for a discussion of the importance of controlling environmental pathogens.) Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated. Appropriate sanitation controls can minimize the presence and transfer of contaminants, including environmental pathogens, to food. The need for sanitation controls related to food workers has long been recognized; however, appreciation of the importance of sanitation controls in preventing contamination due to environmental pathogens is more recent. We request comment on whether proposed § 117.135(d)(3) should be more explicit about the two most common environmental pathogens (i.e., *Salmonella* spp. and *L. monocytogenes*)—e.g., by including these two environmental pathogens as examples.

To make clear that sanitation controls are required when a microorganism of public health significance is a hazard reasonably likely to occur in an RTE food due to employee handling, proposed § 117.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. Sanitation controls have long been used to prevent cross-contamination with pathogens (such as *Staphylococcus aureus* or enteric pathogens such as *Salmonella* spp.) that may be introduced by workers. People are common carriers of *S. aureus*—at any time up to 50 percent of humans will be carriers of this organism (e.g., in the nose and on the skin) (Ref. 161). People are also a source of enteric pathogens, including both symptomatic and asymptomatic infected workers (Ref. 162). Workers can contaminate RTE foods during handling, which can result in foodborne illness, in particular if the food is then held at temperatures that support growth and, in the case of *S. aureus,* production of enterotoxin (Ref. 161) (Ref. 163). Appropriate sanitation controls can minimize the transfer of microorganisms of public health significance from workers to food.

To make clear that sanitation controls are required when a food allergen hazard is reasonably likely to occur, proposed § 117.135(d)(3)(i) includes this circumstance as an example where sanitation controls would be required. As discussed in section IX.D of this document, cross-contact can occur in a facility that manufactures, processes, packs or holds a food that contains a major food allergen and other food that does not contain that allergen. Appropriate sanitation controls can minimize the transfer of food allergens that result in cross-contact.

Proposed § 117.135(d)(3)(i)(A) and (B) would implement section 418(c) of the FD&C Act. Proposed § 117.135(d)(3)(i)(A) also is consistent with the recommendation of the Food CGMP Working Group that food processors be required to develop and maintain, at a minimum, written sanitation procedures for all food-contact equipment and food-contact surfaces (Ref. 1). Under proposed § 117.135(b), the preventive controls for sanitation required by proposed § 117.135(d)(3)(i)(A) and (B) would have to be written.

HACCP plans, as described in the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP Annex (Ref. 35), and Federal HACCP regulations for seafood, juice, and meat and poultry (§ 123.6, § 120.7, and 9 CFR part 417, respectively) require that control measures be established at CCPs to address hazards that are reasonably likely to occur. Because sanitation covers the entire processing environment, not just at CCPs, and is not limited to hazards reasonably likely to occur, sanitation controls have been difficult to fit into HACCP plans and are often addressed using prerequisite programs (e.g., SSOPs). The NACMCF HACCP guidelines (Ref. 34) and the Codex HACCP Annex (Ref. 35) address sanitation measures as prerequisite programs and are silent on their inclusion in HACCP plans to address identified hazards. FSIS addresses sanitation controls for meat and poultry products in a separate sanitation regulation (9 CFR part 416), which is similar to our CGMPs in current part 110 except that it includes SSOP requirements that, unlike our SSOPs, require written sanitation procedures.

In our HACCP regulations for seafood and juice, FDA provides processors with an option to include sanitation controls in their HACCP plans (§§ 123.6(f) and 120.8(c), respectively). Our HACCP regulations require monitoring for eight specified sanitary conditions and practices (referred to as SSOPs) regardless of whether these conditions and practices are related to hazards that are reasonably likely to occur (§§ 123.11(b) and 120.6(a) and (b), respectively). The eight conditions and practices are:

• Safety of the water that comes into contact with food or food-contact surfaces or that is used in the manufacture of ice;
• Condition and cleanliness of food-contact surfaces, including utensils, gloves, and outer garments;
• Prevention of cross contamination from insanitary objects to food, food packaging material, and other food-contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
• Maintenance of hand washing, hand sanitizing, and toilet facilities;
• Protection of food, food packaging material, and food-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
• Proper labeling, storage, and use of toxic compounds;
• Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food-contact surfaces; and
• Exclusion of pests from the food plant.

The PMO HACCP Appendix essentially includes the same requirements as described in the HACCP regulation for juice (part 120) with respect to the eight conditions and practices. However, in the PMO HACCP Appendix these conditions and practices are referred to as ''required prerequisite programs (PPs)'' rather than SSOPs.

The eight areas for which sanitation monitoring is required in our HACCP regulations for seafood and juice are those elements of sanitation in current part 110 that we identified as the most likely to have an impact on the safety of food. FDA's HACCP regulations impose mandatory monitoring, corrective action and recordkeeping for these activities to provide a framework to help ensure that the provisions of current part 110 that relate to the eight specific elements of sanitation are addressed in a systematic way, resulting in greater compliance with those provisions.

The HACCP regulation for seafood recommends but does not require that processors develop written SSOPs for the eight areas of sanitation (§ 123.11(a)). The HACCP regulation for juice requires that an SSOP be developed for these areas but does not require that it be written (§ 120.6(a)). In contrast, proposed § 117.135(d) would require written procedures for identified areas of sanitation and, in addition to monitoring and corrective actions as required in seafood and juice HACCP for the eight areas of sanitation, proposed § 117.135(d) would require monitoring procedures and verification activities.

In considering the application of preventive controls to the eight sanitation controls and practices, we considered the different framework for sanitation controls under this regulation (e.g., the additional requirements) as compared to the juice and seafood HACCP regulations, the traditional role of SSOPs as part of prerequisite programs, and the broad diversity of the food industry covered by this regulation. We tentatively conclude that it is necessary to require that the two areas included in proposed § 117.135(d)(3) be addressed as preventive controls under subpart C and therefore be subject to requirements such as mandatory written procedures. Further, we tentatively conclude that for each of the other six areas, the current CGMPs are sufficient to address any hazards and further requirements in subpart C are not necessary. For these six areas, the value of mandating written procedures and other additional requirements (e.g., written monitoring procedures and verification) would not be significant because the relevant CGMP provisions in essence serve as the written procedures to which the facility must adhere. Some facilities may find value in adding more detail to the material contained in subpart B, but FDA has tentatively concluded that that would not be necessary in order to ensure that the hazards that are reasonably likely to occur are significantly minimized or prevented.

For example, one of the six areas of sanitation is the safety of water used in food operations. In many facilities, the water is supplied by a municipal water authority that monitors the water and alerts its customers of any safety problems. Where facilities use well water, monitoring usually consists of an annual collection and analysis of the water for microbiological (and sometimes also chemical and radiological) safety. Another of the six areas contains provisions that ill workers must be excluded from operations where their presence could lead to contamination of food. A requirement in this regulation to develop written procedures for ensuring that this condition is met does not appear to be necessary, given the rather straightforward and universal nature of the controls (i.e., observe employees for signs of illness and redirect their activities accordingly). Similarly, procedures for ensuring the cleanliness of rest rooms or checking for the presence of pests appear to be unnecessary, given the rather straightforward and universal nature of the controls.

On the other hand, equipment cleaning procedures, as would be required by proposed § 117.135(d)(3)(i)(A) are very specific to the construction of the equipment, the nature of the food, the physical characteristics of the water used, the concentration of cleaning and sanitizing chemicals, the method of application, and the cleaning and sanitizing interval, among other things. For this reason, the procedures must be clearly stated to ensure that they are consistently followed. Often these procedures are performed by contract staff, often during night shifts where management is less likely to be present. In these circumstances, explicit cleaning procedures are essential.

Procedures to prevent cross-contact and cross-contamination, as required by proposed § 117.135(d)(3)(i)(B) are similarly complex and very situational. Identifying product and traffic flow within the facility, employee hand washing and sanitizing, and employee garbing requirements is critical to ensure that employees are trained on the correct procedures to ensure product safety.

Proposed § 117.135(d)(3)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 117.135(d)(3)(i)(A) or (B). Proposed § 117.135(d)(3)(ii) is consistent with our HACCP regulations for seafood and juice, which each require that the processor correct, in a timely manner, those sanitation conditions and practices that are not met (§§ 123.11(b) and 120.6(b), respectively). Proposed § 117.135(d)(3)(ii) also is consistent with 9 CFR part 416, which requires, in general, that each establishment take appropriate corrective action(s) when the establishment's SSOPs or the implementation or maintenance of the SSOPs, may have failed to prevent direct contamination or adulteration of product(s); corrective actions must include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOPs or appropriate improvements in the execution of the SSOPs (9 CFR 416.15).

Proposed § 117.135(d)(3)(iii) would provide that the owner, operator, or

agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 117.135(d)(3)(ii), to correct conditions and practices that are not consistent with the procedures in proposed § 117.135(d)(3)(i) (A) or (B). As discussed in sections XII.F.2 and XII.F.3 of this document, proposed § 117.145(a) would require that the owner, operator or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, and outlines specific components that must be included. Proposed § 117.145(b) would require specific actions in the event of an unanticipated problem when a preventive control is not properly implemented and a specific corrective action procedure has not been established or a preventive control is found to be ineffective. For sanitation controls, proposed § 117.135(d)(3)(ii) would require that the owner, operator or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the established sanitation control practices.

There are many different ways in which conditions and practices for sanitation can deviate from the established procedures. In many instances the actions taken will be the same, regardless of the deviation. The corrective actions will generally involve re-establishing sanitary conditions (e.g., re-cleaning a piece of equipment) and/or retraining personnel to carry out the procedures correctly. In many instances the procedural deviations are not reasonably likely to impact product (e.g., insanitary food-contact surfaces are usually detected by a pre-production inspection of the equipment by plant personnel; deviations in cleaning solution strength rarely result in the production of unsafe product if other cleaning and sanitizing procedures were properly carried out). Thus, there is rarely a need to evaluate the impact of the sanitation failure on food and to prevent food from entering commerce, as would be required by proposed § 117.145(a)(2)(ii) and (iii). Because the corrective actions that will need to be taken for most sanitation controls are so general, we see little benefit in requiring a facility to develop written corrective action procedures for the many sanitation deviations that could occur. We do expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 117.135(d)(3)(ii). The requirement in proposed § 117.135(d)(3)(ii) to take action to correct, in a timely manner, sanitation conditions and practices that are not in accordance with procedures is consistent with proposed § 117.145(a)(2)(i), which would require that appropriate action be taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur.

Proposed § 117.135(d)(3)(iv) would require that all corrective actions taken in accordance with proposed § 117.135(d)(3)(ii) be documented in records that would be subject to verification in accordance with proposed § 117.150(c) and records review in accordance with proposed § 117.150(d)(2)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

8. Proposed § 117.135(d)(4)—Recall Plan

Proposed § 117.135(d)(4) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 117.137. Proposed § 117.135(d)(4) would incorporate the statutory definition of ''preventive controls'' from section 418(o)(3)(E) of the FD&C Act, which establishes that preventive controls may include a recall plan. We include the details of the recall plan in proposed § 117.137 and discuss it in section XII.D of this document.

9. Proposed § 117.135(d)(5)—Other Controls

Proposed § 117.135(d)(5) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 117.135(a)—i.e., to significantly minimize or prevent hazards identified in the hazard analysis and to provide assurance that the food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. For example, if a facility produces a refrigerated product that could support the growth of pathogens if proper temperature is not maintained during transportation, the facility must consider the need to implement preventive controls to minimize or prevent the potential for pathogen growth due to failure to control the temperature of the product during transportation. Most instances of failing to control temperature result primarily in quality issues such as product degradation or shortened shelf life, rendering the product unpalatable and thus precluding consumption. However, it is not common that products reach high enough temperatures for sufficient time to become hazardous due to growth of pathogens that may be present. For products that present a risk that pathogens would grow and present a health hazard, preventive controls could include temperature monitoring during transportation or other procedures that would ensure that product was not exposed to temperature/time intervals during transportation that would result in increased product temperatures for sufficient time to result in a potential safety issue. Often such procedures involve the shipper ensuring that product temperature is controlled during loading of the transportation vehicle, use of temperature recording devices that record the temperature of the transportation compartment during transportation, and the receiver verifying the temperature of product during transit as displayed by the temperature device.

FDA notes that some of the controls listed in section 418(o) of the FD&C Act are not explicitly identified in proposed § 117.135. In section XII.J of this document, we request comment on an environmental monitoring program (which section 418(o)(3)(C) of the FD&C Act indicates is one of the procedures, practices, and processes that preventive controls may include, and which section 418(f)(4) of the FD&C Act identifies as a verification activity). In section XII.J of this document, we also request comment on a supplier approval and verification program as one of the procedures, practices, and processes that preventive controls may include (section 418(o)(3)(G)). In section XI.M, of this document, we request comment on supervisor, manager, and employee hygiene training. We discuss CGMPs in section XI of this document. Further, as discussed in section XII.C.7 of this document, training and CGMP controls are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in proposed part 117, subpart B will be sufficient. However, a facility may determine that in some circumstances it would be appropriate to include certain Current Good Manufacturing Practice provisions among their preventive

controls (i.e., as ''other controls'' in proposed § 117.135(d)(6)).

10. Proposed § 117.135(e)—Applicability of Monitoring, Corrective Actions, and Verification

Proposed § 117.135(e)(1)(i) through (iii) would specify that, except as provided by proposed § 117.135(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 117.140; corrective actions as would be required by proposed § 117.145; and verification as would be required by proposed § 117.150. Proposed § 117.135(e)(1)(i) through (iii) would restate the requirements of proposed §§ 117.140, 117.145, and 117.150 to clearly communicate the applicability of proposed §§ 117.140, 117.145, and 117.150 to the preventive controls that would be required under proposed § 117.135 and would establish no new requirements.

Proposed § 117.135(e)(2) would provide that the recall plan that would be established in proposed § 117.137 would not be subject to the requirements of proposed § 117.135(e)(1). A recall plan would address food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at food while it remains at the facility. Thus, as proposed, the requirements for monitoring, corrective actions, and verification have limited applicability to a recall plan. However, a ''mock recall'' (i.e., a simulated recall situation) is a verification activity that could identify problems with a recall plan, enable a facility to correct the problems, and provide reasonable assurance that the recall plan would be effective in removing products from commerce. FDA requests comments on whether to include a requirement for a mock recall as verification activity in the final rule.

D. Proposed § 117.137—Recall Plan for Food With a Hazard That Is Reasonably Likely To Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented (section 418(c)(1) of the FD&C Act); and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (section 418(c)(3) of the FD&C Act).

Under section 418(o)(3)(D), the procedures, practices, and processes described in the definition of preventive controls may include, in relevant part, a recall plan.

2. Proposed § 117.137—Recall Plan for Food With a Hazard That is Reasonably Likely To Occur

Proposed § 117.137(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for food in which there is a hazard that is reasonably likely to occur. Although a recall is different from other preventive controls in that it is carried out after a product is distributed, it shares the purpose of significantly minimizing or preventing hazards, which is accomplished by limiting consumption of the affected food. Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall; additional time during which the food is on the market can result in additional consumer exposure. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked.

Proposed § 117.137(a) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3)(E) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex GPFH. The NACMCF HACCP guidelines recommend that a recall system be in place (Ref. 34). The GPFH recommends that managers ensure effective procedures are in place to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. 44). Our HACCP regulations for seafood and juice do not include any requirements for a recall plan; recommendations for addressing a recall for food can be found in our general guidance on policy, procedures, and industry responsibilities regarding recalls in subpart C of part 7 (§§ 7.40 through 7.59). The guidance advises firms to prepare and maintain a current written contingency plan for use in initiating and effecting a recall (§ 7.59). Likewise, the FSIS HACCP regulation for meat and poultry does not require a recall plan; FSIS addresses recalls through guidance to industry.

Proposed § 117.137(b) would require that the recall plan include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

- Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected food (proposed § 117.137(b)(1));
- Notify the public about any hazard presented by the food when appropriate to protect public health (proposed § 117.137(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (proposed § 117.137(b)(3)); and
- Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food (proposed § 117.137(b)(4)).

Procedures that describe the steps to be taken would enable a facility to act promptly by following its plan when the facility determines that a recall is warranted rather than developing a plan of action after the need for a recall is identified. Procedures that assign responsibility for taking those steps would save the time needed to make such determinations during a recall and enable the owner, operator, or agent in charge of a facility to clearly communicate such responsibilities to applicable managers or staff so that such managers or staff can take action as soon as the decision to conduct a recall is made.

Directly notifying direct consignees about the recall (proposed § 117.137(b)(1)) is the most effective mechanism to ensure direct consignees know that the product is being recalled and is consistent with our general guidance on recall communications in § 7.49(a). Further, instructing direct consignees how to return or dispose of an affected product minimizes the chance the affected product will be disposed of improperly and allows direct consignees to act quickly. Further, it is consistent with our guidance on the content of recall communications in § 7.49(c)(4). We have provided guidance to industry on model recall letters (Ref. 164) (Ref. 165). This guidance may be useful in developing procedures for directly notifying direct consignees about the recall and on how to return or dispose of an affected product.

Notification procedures could identify a variety of communication means, including email, telephone, fax, text messaging, and urgent mail delivery. Notification procedures that would establish only a general notification to the public (e.g., through a press release or through information posted on a facility's Web site), without procedures

for concurrent contact directly with direct consignees about how to access the general notification, would not satisfy proposed § 117.137(b)(1); a general notification to the public would rely on the chance that the direct consignees would see the information and may not be effective.

Notifying the public about any hazard presented by the food when appropriate to protect public health is a common practice (e.g., see FDA's Web site that provides information gathered from press releases and other public notices about recalls of food (Ref. 166)). Notifying the public in such circumstances is consistent with our guidance on a recall strategy that the purpose of a public warning is to alert the public that a product being recalled presents a hazard to health (§ 7.42(b)). Notifying the public, in addition to direct consignees, may not be necessary to protect the public if, for example, the food being recalled was all distributed to food service operations (who were notified as a direct consignee) and not distributed for retail sale. Procedures in the recall plan for notifying the public could include model press releases and procedures for disseminating information to the public though press releases or other means, such as by information posted on the facility's Web site or provided to consumers using social media. We have provided guidance to industry with examples of model press releases for the presence in food of undeclared food allergens and several foodborne pathogens, including *Salmonella* spp. and *L. monocytogenes* (Ref. 164) (Ref. 165) (Ref. 167) (Ref. 168) (Ref. 169).

An effectiveness check is a procedure designed to verify that all notified consignees have received notification about the recall and have taken appropriate action; procedures to conduct effectiveness checks would be consistent with our guidance on a recall strategy in § 7.42(c)(3). Procedures to conduct an effectiveness check could expand on the procedures used to directly contact consignees about the recall—e.g., to include forms for consignees to provide information about the amount of recalled product on hand, to include information on follow up contacts via phone or email, or to include personal visits to consignees by sales representatives. We have provided guidance to industry on conducting effectiveness checks (Ref. 164); this guidance includes a model effectiveness check letter (Ref. 170), a model effectiveness check response form that could be sent to a consignee (Ref. 171), and a model questionnaire to be used during effectiveness checks conducted by telephone or by personal visit (Ref. 172).

A facility that receives recalled product from their customers must appropriately dispose of the product—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the product. These types of disposition actions are similar to the disposition actions that a facility would consider as a corrective action as a result of a problem that is discovered before the product leaves the facility (see, e.g., the discussion of corrective actions in the final rule to establish our HACCP regulation for seafood; 60 FR 65096 at 65127). Procedures for disposition of a product can help the facility ensure that disposition of recalled product will be appropriate and will not present a risk to consumers. Implementation of such procedures is part of determining whether a recall can be considered terminated. Thus, having procedures in place can result in more efficient completion of a recall. Under § 7.55, appropriate disposition of recalled product is a consideration in determining whether a recall is terminated.

We request comment on whether the procedures to be included in the recall plan (i.e., to directly notify consignees, to notify the public, to conduct effectiveness checks and to appropriately dispose of recalled product) are appropriate for all types of facilities or if they should be modified for certain facilities.

We request comment on whether we should require a recall plan to include procedures and assignments of responsibility for notifying FDA of recalls subject to the plan. Notifying FDA could enhance the effectiveness of a recall by allowing FDA to take appropriate steps to minimize the risk of illness or injury related to recalled products. As discussed in section II.A.6 of this document, notifying FDA of a reportable food is required by section 417 of the FD&C Act. Reportable food reports include information about whether a reportable food is being recalled. Thus, in some cases, reporting a recall to FDA could be accomplished by submitting a reportable food report required under section 417. In other cases, facilities could notify the local FDA district office of the recall.

E. Proposed § 117.140—Monitoring

1. Requirements of Section 418 of the FD&C Act

Section 418(a) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the performance of the preventive controls. Section 418(d) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act to provide assurances that the outcomes described in section 418(c)] shall be achieved. The outcomes relevant to this proposal are those that provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that food manufactured, processed, packed or held by a facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Section 418(g) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act.

Section 418(h) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act.

2. Monitoring in HACCP Systems

Proposed § 117.3 would define ''monitor'' to mean ''to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.'' We discussed this definition, and how it is used in HACCP systems, including in guidelines developed by NACMCF and Codex, in section X.B.4 of this document. Examples of monitoring activities include: visual observation and measurement of temperature, time, pH, and moisture level (Ref. 34). The NACMCF HACCP guidelines identify three purposes of monitoring (Ref. 34). First, monitoring is essential to managing food safety because it facilitates tracking of the operation (i.e., the ''process, point or procedure'' that is being controlled). This provides ongoing information about whether the process, point or procedure is under control (i.e., operating according to plan), and can provide information about shifts away from control. If monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a deviation from a critical limit occurs. For example, if the temperature needed to ensure safety of roasted nuts

is 290 °F, and the procedure for roasting the nuts in an oil roaster calls for an operating temperature of 350 °F, monitoring would detect that the temperature in the oil roaster was dropping and enable the facility to identify and fix the problem with temperature before the temperature drops to 290 °F. Second, monitoring is used to determine when a deviation occurs at a critical control point (i.e., exceeding or not meeting a critical limit), indicating there is loss of control. In the previous example, there would be loss of control if the temperature drops to 289 °F. When a deviation occurs, an appropriate corrective action must be taken—e.g., stop the roasting process until the temperature in the oil roaster can be maintained above 290 °F and reprocess nuts that were not roasted at the appropriate temperature. Third, monitoring provides written documentation for use in verification. For example, if the facility monitors the temperature of the oil roaster continuously, using a temperature recording device, the output of the temperature recording device is available during the verification activity of review of records. Under this approach, monitoring is directed to evaluating implementation of the preventive controls, and the written documentation of the monitoring is then used in verification.

3. Verification in HACCP Systems

Proposed § 117.3 would define ''verification'' to mean ''those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.'' We discussed this definition, and how it is used in HACCP systems, in section X.B.4 of this document. The NACMCF HACCP guidelines identify several aspects of verification (Ref. 34). One aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. Both of these aspects are directed at the effectiveness of a preventive control; they establish that the preventive control is scientifically valid for controlling the hazard and verify that the preventive control is accomplishing its intended purpose. The Codex HACCP Annex addresses verification as determining compliance with the HACCP plan and confirming that the HACCP system is working effectively (Ref. 35). Examples of verification activities include review of monitoring records and review of records for deviations and corrective actions. We discuss verification activities in more detail during our discussion of proposed § 117.150 (Verification) in section XII.G of this document.

4. Relationship Between Monitoring and Verification

Monitoring and verification are closely related; both address the performance of preventive controls, and verification relies in part on monitoring records to establish that preventive controls developed to significantly minimize or prevent hazards are being implemented according to plan. Three provisions of section 418(f) of the FD&C Act (Verification) are particularly relevant when considering the role of monitoring. First, section 418(f)(1) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the preventive controls implemented * * * are adequate to control the hazards identified.* * *'' Second, section 418(f)(2) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the owner, operator, or agent is conducting monitoring.* * *'' Third, section 418(f)(4) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the preventive controls implemented * * * are effectively and significantly minimizing or preventing the occurrence of identified hazards.* * *''

5. Monitoring the Performance of Preventive Controls

Section 418(a) requires monitoring the ''performance'' of preventive controls whereas section 418(d) requires monitoring their ''effectiveness.'' We tentatively conclude that the language of section 418 regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the performance of preventive controls. ''Performance'' means ''the execution or accomplishment of an action, operation, or process undertaken or ordered'' (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 2157) and is consistent with use of the term ''monitoring'' in traditional HACCP. Monitoring the performance of preventive controls would be undertaken to determine whether a facility is implementing its preventive controls and would generate records that would be used to verify implementation of the controls. For example, monitoring performance could include visual observations and measurements of temperature, time pH, and moisture level. In contrast, ''effectiveness'' refers to the quality of ''having an effect or result'' (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 794) and is not consistent with use of the term ''monitoring'' in traditional HACCP. The term ''verification,'' not ''monitoring'' is used to refer to effectiveness in traditional HACCP systems. Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working.

Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. Section 418(f) requires verification that the preventive controls ''are effectively and significantly minimizing the occurrence of the identified hazards.* * *'' The activities necessary for such verification are the same as would be required for monitoring the effectiveness of the preventive controls. For example, because effectiveness addresses whether the hazard is controlled, monitoring the effectiveness could include testing for the presence of the hazard, such as testing for the presence of staphylococcal enterotoxin that can occur during cheese making if the pH does not drop to a low enough level in a short enough time. Further, requiring monitoring of effectiveness rather than performance of the preventive controls would create a significant gap in the preventive controls system if the factors that are critical to control of the hazard, e.g., pH of the cheese curd and time, are not monitored to ensure the process is implemented correctly. In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately (e.g., pH of the cheese curd drops below 5.6 within 8 hours) and thereby are effectively and significantly minimizing or preventing the hazards (e.g., staphylococcal enterotoxin).

As discussed more fully in the next section of this document, this interpretation also is grounded in our existing HACCP regulations and guidance. Section 418(n)(5) of the FD&C Act directs the Secretary, in promulgating these regulations, to review hazard analysis and preventive control programs in existence to ensure that this regulation is consistent to the extent practicable with applicable domestic and internationally-recognized standards in existence. Requiring monitoring of the performance of preventive controls is consistent with

applicable domestic and internationally recognized standards.

Therefore, we tentatively conclude that this interpretation is reasonable, and we propose to adopt it in the proposed requirements implementing section 418(d) of the FD&C Act. We request comment on this interpretation.

6. Proposed § 117.140—Monitoring

a. Proposed § 117.140(a)—Requirement for written procedures for monitoring. Proposed § 117.140(a) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. Proposed § 117.140(a) would implement sections 418(d) and (h) of the FD&C Act.

Proposed § 117.140(a) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. We discuss the purposes that the NACMCF HACCP guidelines identify for monitoring under a HACCP system in section II.C.4.d of this document. Each of these purposes applies to preventive controls as well, and we tentatively conclude that these purposes would be achieved by proposed § 117.140(a). Proposed § 117.140(a) would facilitate tracking the implementation of the preventive controls to provide assurance that they are consistently performed; if monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a preventive control is not properly implemented and potentially unsafe product is produced. Further, if monitoring is conducted with sufficient frequency to ensure preventive controls are consistently performed, it will detect if a preventive control is not properly implemented (e.g., if the temperature of an oven falls below the temperature needed to ensure safety), indicating loss of control and signaling the need for an appropriate corrective action. Finally, the proposed monitoring requirement would result in written documentation for use in verification.

The Codex HACCP Annex advises that monitoring procedures must be able to detect loss of control at the CCP and ideally should provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. The Codex HACCP Annex also recommends that, where possible, process adjustments be made when monitoring results indicate a trend towards loss of control at a CCP, before a deviation occurs (Ref. 35). Federal HACCP regulations for seafood, juice, and meat and poultry require in the written HACCP plan monitoring of control measures to determine whether physical, chemical, or biological parameters are being met (i.e., monitoring of critical control points to ensure compliance with the critical limits) (§ 123.6(b) and (c)(4)), § 120.8(a) and (b)(4), and 9 CFR 417.2(b)(1) and (c)(4), respectively). Like the Federal HACCP regulations for seafood, juice, and meat and poultry, the requirements for monitoring in proposed § 117.140(a) focus on evaluating performance of the preventive controls.

Proposed § 117.140(a) would require that the monitoring procedures be written. Under section 418(d) of the FD&C Act, the owner, operator, or agent in charge of a facility must monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act, and under section 418(h) of the FD&C Act the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act must be included in the written plan. The NACMCF HACCP guidelines note under record-keeping and documentation procedures that the procedures for monitoring should be provided (Ref. 34). The Codex HACCP Annex includes ''monitoring procedures'' in its example of a HACCP worksheet (Ref. 35). Federal HACCP regulations for seafood, juice and meat and poultry require that the HACCP plan be written (§§ 123.6(b), 120.8(a), and 9 CFR 417.2(b)(1), respectively) and that procedures for monitoring be included in the written HACCP plan (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

Proposed § 117.140(a) would require that the monitoring procedures include the frequency with which they are to be performed. We discuss the frequency of monitoring in the next section of this document. Briefly, the frequency of monitoring must be sufficient to ensure that the preventive control is consistently performed in order to help ensure that the preventive control is effective. The NACMCF HACCP guidelines note that the frequency of monitoring should be provided in the HACCP Plan Summary Table (Ref. 34). Federal HACCP regulations for seafood, juice and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively).

b. Proposed § 117.140(b)—Frequency of monitoring. Proposed § 117.140(b) would require that the owner, operator, or agent in charge of a facility monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed. Proposed § 117.140(b) does not specify a single monitoring frequency applicable to all facilities and processes. Rather, it requires monitoring with ''sufficient frequency'' to assure that the preventive controls are consistently performed. Proposed § 117.140(b) would implement section 418(d) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex.

The NACMCF guidelines recommend continuous monitoring where possible (Ref. 34). Continuous monitoring is possible with many types of physical and chemical parameters. For example, the temperature and time for many thermal processes can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the affected product can be retained and evaluated to determine the appropriate disposition. Examples of other parameters that can be monitored continuously include pressure, flow rate and pH.

However, the NACMCF guidelines acknowledge that continuous monitoring may not be possible, or even necessary, in all cases. For example, it may not be practical to continuously monitor the size of particles in a food to ensure they do not exceed the maximum dimensions that are required to ensure a process such as cooking, cooling, or acidification can be properly implemented. NACMCF states that if monitoring is not continuous it may be difficult to ensure that the preventive controls are consistently implemented and a problem has not occurred. Thus, according to NACMCF, the frequency of non-continuous monitoring must be sufficient to ensure that a critical control point (or, in the case of this proposed rule, a preventive control) is under control (Ref. 34). The Codex HACCP Annex also notes that, if monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control (Ref. 35). The frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process. For example, if the temperature needed to ensure safety of roasted nuts is 290 °F, non-continuous monitoring would need to be more frequent when an oil roaster for nuts is operated at 300 °F than when the oil roaster is operated at 350 °F. As another example, if temperatures vary

by 10–15 °F during processing, monitoring would need to be more frequent than if the variation is only 1–2 degrees.

As discussed in the previous section of this document, Federal HACCP regulations for seafood, juice, and meat and poultry require that the written HACCP plan include the procedures, and frequency thereof, that will be used for monitoring (§§ 123.6(c)(4), 120.8(b)(4), and 9 CFR 417.2(c)(4), respectively). Our Fish and Fishery Products Hazards and Controls Guidance discusses the frequency of monitoring and notes that the frequency of monitoring depends upon the circumstances, with continuous monitoring being desirable; in some cases, continuous monitoring may be necessary, while in other cases, it may not be necessary or practical (Ref. 173). Our Juice HACCP Hazards and Controls Guidance provides examples of ''Summary HACCP Plans,'' which show how the frequency of monitoring would depend on the circumstances (Ref. 4).

c. Proposed § 117.140(c)—Requirement for records. Proposed § 117.140(c) would require that all monitoring of preventive controls in accordance with proposed § 117.140 be documented in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with proposed § 117.150(d)(2)(i). Proposed § 117.140(c) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan (Ref. 34). The Codex HACCP Annex gives records of CCP monitoring activities as an example of records (Ref. 35). Our HACCP regulations for seafood and juice require that the HACCP plan provide for a recordkeeping system that documents the monitoring of the critical control points (§§ 123.6(c)(7) and 120.8(b)(7), respectively). The FSIS HACCP regulation for meat and poultry requires records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values.

The monitoring records would be used to verify that the preventive controls are adequate, as would be required by proposed § 117.150(a), and to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, as would be required by proposed § 117.150(d). This is further discussed in section XII.G.5.b of this document. Together, proposed §§ 117.140(a), (b), and (c) and 117.150(a), (b), and (d) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

F. Proposed § 117.145—Corrective Actions

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act. Section 418(e) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective:

- Appropriate action is taken to reduce the likelihood of recurrence of the implementation failure (section 418(e)(1) of the FD&C Act);
- All affected food is evaluated for safety (section 418(e)(2) of the FD&C Act); and
- All affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (section 418(e)(3) of the FD&C Act).

Section 418(f)(4) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility verify that the preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards.

2. Proposed § 117.145(a)—Corrective Action Procedures

Proposed § 117.145(a)(1) would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Having written procedures in place would enable facilities to act quickly and appropriately when preventive controls are not properly implemented—e.g., when a parameter associated with heat processing exceeds a maximum value or falls below a minimum value. Proposed § 117.145(a)(1) would implement section 418(e) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

The NACMCF HACCP guidelines define a corrective action as procedures followed when a deviation occurs at a CCP and recommend that specific corrective actions be developed in advance for each CCP and included in the HACCP plan (Ref. 34). The Codex HACCP Annex advises that specific corrective actions be developed for each CCP in the HACCP system (Ref. 35). Our HACCP regulations for seafood and juice require that processers take corrective action whenever a deviation from a critical limit occurs, either by following specific corrective action procedures specified in the regulation, or by following procedures in written corrective action plans that the processor develops (§§ 123.7 and 120.10, respectively). If the processor of a seafood or juice product covered by the applicable HACCP regulation develops such plans, they must be included in the written HACCP plan (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5), respectively). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

As discussed in section XII.C.4 of this document, the proposed rule would establish requirements for preventive controls (which may be at critical control points), and proposed § 117.135(c)(2) would require that the preventive controls include, as appropriate to the facility and the food, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur (which reflects the NACMCF definition of a critical limit). As already noted earlier in this section, if a parameter associated with heat processing falls below a minimum value, corrective action would be triggered. Thus, the concept in the proposed rule of taking corrective action when a preventive control is not properly implemented is

similar to the concept in HACCP systems of taking corrective action for a deviation from a critical limit at a critical control point.

The benefits from identifying corrective action procedures in advance of the need to actually take corrective action largely derive from having the procedures in written form. Written corrective action procedures would be essential to the facility's food safety team, to auditors, and to inspectors. The facility's food safety team will be responsible for ensuring that appropriate corrective actions are taken if preventive controls are not properly implemented. Having access to appropriate, written corrective action procedures determined in advance of the need for such action can ensure that correct and complete actions are taken in a timely fashion without the need for the team to meet and decide on the appropriate action. Having written corrective action procedures available for auditors and for inspectors is essential for them to assess the adequacy of the food safety plan; the procedures a facility will use to address implementation failures are essential to the production of safe food, and without them a complete assessment cannot be made. Written corrective action procedures also would be useful for training purposes, so that employees who would need to implement the corrective action procedures will be prepared for what they would need to do.

Proposed § 117.145(a)(2) would implement section 418(e) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must establish corrective action procedures) and section 418(h) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must prepare a written plan). Proposed § 117.145(a)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and with Federal HACCP regulations for seafood, and juice, and meat and poultry. The NACMCF HACCP guidelines recommend that specific corrective actions be included in the HACCP plan (Ref. 34). In its discussion of corrective actions, the Codex HACCP Annex advises that deviation and product disposition procedures be documented in the HACCP record keeping (Ref. 35). Our HACCP regulations for seafood and juice both require that the written HACCP plan include any corrective action plans that have been developed by the processor (§§ 123.6(c)(5) and 123.7(b) and 120.8(b)(5)). The FSIS HACCP regulation for meat and poultry requires that the written HACCP plan identify the corrective action to be followed in response to a deviation from a critical limit (9 CFR 417.3(a)).

Proposed § 117.145(a)(2) would require that corrective action procedures describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur (proposed § 117.145(a)(2)(i));
- All affected food is evaluated for safety (proposed § 117.145(a)(2)(ii)); and
- All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 117.145(a)(2)(iii)).

The hazard analysis and risk-based preventive controls in this proposed rule are designed to identify hazards that are reasonably likely to occur, and to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. However, a preventive controls system, similar to a HACCP system (Ref. 34), accounts for the possibility of implementation and effectiveness problems and includes procedures for addressing those problems and any affected food.

Proposed § 117.145(a)(2) would implement sections 418(e)(1)-(3) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that corrective actions include elements to determine and correct the cause of non-compliance and to determine the disposition of non-compliant product (Ref. 34). The Codex HACCP Annex advises that the specific corrective actions must ensure that the CCP has been brought under control and that actions taken must also include proper disposition of the affected product (Ref. 35). Our HACCP regulations for seafood and juice establish that a corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and the cause of the deviation is corrected (§§ 123.7(b) and 120.10(a), respectively). The FSIS HACCP regulation for meat and poultry requires that the HACCP plan describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) the CCP will be under control after the corrective action is taken; (3) measures to prevent recurrence are established; and (4) no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce (9 CFR 417.3(a)).

Section 418(e)(1) of the FD&C Act and proposed § 117.145(a)(2)(i) explicitly require that action be taken to reduce the likelihood of recurrence of the implementation failure. Although not prescribed by proposed § 117.145(a)(2)(i), reducing the likelihood of recurrence of an implementation failure is best accomplished by identifying the root cause of failure and then taking action to address that root cause. If the root cause is not identified and corrected, it is more likely that the failure will recur. For example, if the temperature of a heat process cannot be maintained, a corrective action to raise the temperature using the controller may correct the problem short-term. However, if the root cause is a lack of boiler capacity to run multiple heating units at the same time, corrective action should address replacing the boiler to increase capacity. Similarly, if a facility cannot cool a food rapidly enough in a refrigerator to meet the cooling times and temperatures in its HACCP plan, the initial corrective action may be to move product into a freezer for cooling. If the root cause is determined to be that the product was filled too high in the cooling tray, the corrective action may be to include procedures to measure the depth of product in the tray. If the root cause is determined to be insufficient cooling capacity to remove heat from the amount of product being cooled, the corrective action may involve using a cooling unit with greater cooling capacity or changing the method of cooling, e.g., to a blast freezer.

Proposed § 117.145(a)(2)(ii) and (iii), would require that corrective action procedures include an evaluation of all food affected by a problem and procedures for ensuring that affected food is prevented from entering into commerce if the owner, operator or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Such an evaluation is implicit in our HACCP regulations for seafood and juice (§§ 123.7(b) and 120.10(a)) in that these

sections do not explicitly require that food affected by the problem be evaluated, but do require that steps be taken to ensure that product that is injurious to health or otherwise adulterated does not enter commerce. Although our HACCP regulations for seafood and juice do not specify the steps that must be described in a corrective action plan, the regulations require that specific steps be taken when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation (§§ 123.7(c) and 120.10(b), respectively). Under these regulations, required steps include segregating and holding effected product, performing or obtaining a review to determine the acceptability of the affected product for distribution and taking corrective action, when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. FDA notes that the corrective action procedures in the HACCP regulations do not reference misbranding under section 403(w) of the FD&C Act. Section 403(w) of the FD&C Act was added to the FD&C Act by the Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108–282, Title II), which was enacted after issuance of both the seafood and juice HACCP regulations. However, our HACCP regulation for juice includes the presence of undeclared ingredients that may be allergens as a potential hazard that must be considered in the hazard analysis (§ 120.7(c)(8)), and our Fish and Fishery Products Hazards and Controls Guidance (Fourth Edition) (Ref. 173) and Juice HACCP Hazards and Controls Guidance (Ref. 4) both include recommendations directed to hazards from undeclared food allergens.

3. Proposed § 117.145(b)—Corrective Action in the Event of an Unanticipated Problem

Proposed § 117.145(b)(1) would require that if a preventive control is not properly implemented and a specific corrective action has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility take corrective action to identify and correct the problem, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under proposed § 117.145(a)(2)(i)–(iii). However, a facility might not anticipate all of the problems that may occur, and a facility may experience an implementation failure for which a corrective action procedure has not been established. Regardless of whether a problem was anticipated and a corrective action procedure was developed in advance, corrective actions to accomplish the steps that would have been included in a corrective action procedure are necessary. Likewise, a facility might determine (e.g., as a verification activity in accordance with proposed § 117.150(d), discussed in section XII.G.5 of this document), that a preventive control is ineffective. For example, detecting a pathogen in an RTE food may signal that preventive controls for that pathogen are ineffective. As in the case of an unanticipated implementation failure of a preventive control, corrective actions would be necessary if a preventive control is found to be ineffective.

Proposed § 117.145(b)(1) is consistent with Federal HACCP regulations for seafood, juice, and meat and poultry. Our HACCP regulations for seafood and juice require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor segregate and hold the affected product; perform or obtain a review to determine the acceptability of the affected product for distribution; take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and take corrective action, when necessary, to correct the cause of the deviation (§§ 123.7(c)(1)–(4) and 120.10(b)(1)–(4), respectively). The FSIS HACCP regulation for meat and poultry (9 CFR 417.3(b)) requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must: (1) Segregate and hold the affected product, at least until the requirements of 9 CFR 417.3(b)(2) and (3) are met; (2) perform a review to determine the acceptability of the affected product for distribution; and (3) take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce. The NACMCF HACCP guidelines and the Codex HACCP Annex are silent on the specific issue of taking corrective actions when a preventive control is not properly implemented and a specific corrective action has not been established or when a preventive control has been found to be ineffective. However, proposed § 117.145(b)(1) is consistent with HACCP principles, discussed earlier in this section, recommended in the NACMCF HACCP guidelines and Codex HACCP Annex regarding the importance of corrective actions whenever there is a deviation from a critical limit. In each of the situations described (following an established corrective action, taking corrective action in the absence of a plan, or taking corrective action when the preventive control is found to be ineffective) the intent of taking corrective action is to restore control and to ensure that hazardous foods do not reach the consumer.

Proposed § 117.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 117.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented and a specific corrective action has not been established, or if a preventive control is found to be ineffective. (We use the term ''reanalyze'' when we refer to a reassessment of the validity of a preventive control or the food safety plan to control a hazard.) Under proposed § 117.150(a), the verification required by section 418(f) of the FD&C Act would include validation of the food safety plan, referring to whether it is effectively controlling the hazards or ''working correctly.'' See section XII.G of this document for a discussion of proposed requirements for verification (including validation and reanalysis) under section 418(f) of the FD&C Act. Proposed § 117.145(b)(2) would apply to unanticipated food safety problems, and the unanticipated nature of the problems is relevant to the reanalysis of the food safety plan. If the owner, operator, or agent in charge of a facility has assessed its procedures, practices, and processes and has not identified a specific failure as a foreseeable occurrence, the owner, operator, or agent in charge must assess whether the problem is simply an implementation failure that could be expected to occur in the normal course of manufacturing, processing, packing or holding the food, or the result of a system-wide problem that is not being properly addressed by the plan (e.g., ineffective preventive controls). If the problem is simply an implementation failure, and such a failure is now a foreseeable circumstance, reanalysis of the food safety plan would be necessary to determine whether a corrective action procedure should be established for that foreseeable failure. Likewise, if the

problem is the result of a system-wide problem that is not being properly addressed by the plan (or is otherwise a result of ineffective preventive controls), reanalysis of the food safety plan would be necessary to identify effective preventive controls. Either way, reanalyzing the food safety plan and modifying it as necessary would be necessary to reduce the risk of recurrence of the problem.

Proposed § 117.145(b)(2) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines, in relevant part, recommend that validations (i.e., an assessment of the validity of the HACCP plan) be conducted when there is an unexplained system failure (e.g., an implementation failure or ineffective preventive controls) (Ref. 34). The Codex HACCP Annex, in relevant part, advises that verification procedures be used to determine if the HACCP system is working correctly (Ref. 35); such verification procedures would also be used if an unexpected implementation failure of a preventive control suggests that the system is not working correctly. Our HACCP regulations for seafood and juice, in relevant part, require that, when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor must perform or obtain timely reassessment or verification by a trained individual to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation and to modify the HACCP plan as necessary (§§ 123.7(c)(5) and 120.10(b)(5), respectively). The FSIS regulation for meat and poultry requires, in relevant part, that if a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment must perform or obtain reassessment to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). (The FSIS HACCP regulation for meat and poultry uses the term ''reassessment'' much as this proposed rule would use the term ''reanalysis.'')

4. Proposed § 117.145(c)—Documentation

Proposed § 117.145(c) would require that all corrective actions taken in accordance with this section be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(2)(i). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

G. Proposed § 117.150—Verification

1. Requirements of Section 418 of the FD&C Act

Section 418(f) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that:

- The preventive controls implemented under section 418(c) of the FD&C Act are adequate to control the hazards identified under [section 418(b) of the FD&C Act (section 418(f)(1) of the FD&C Act);
- The owner, operator, or agent is conducting monitoring in accordance with section 418(d) of the FD&C Act (section 418(f)(2) of the FD&C Act);
- The owner, operator, or agent is making appropriate decisions about corrective actions taken under section 418(e) of the FD&C Act (section 418(f)(3) of the FD&C Act);
- The preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means (section 418(f)(4) of the FD&C Act); and
- There is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f)(5) of the FD&C Act).

In addition, section 418(g) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Further, section 418(i) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall conduct a reanalysis under section 418(b) of the FD&C Act (the requirement to identify and evaluate known or reasonably foreseeable hazards) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. The owner, operator, or agent shall revise the written plan required under section 418(h) of the FD&C Act if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

2. Proposed Requirements for Validation

a. Proposed § 117.150(a)—Validation that preventive controls are adequate to control the hazard. Proposed § 117.150(a) (Validation) would require that, except as provided by paragraph (a)(3), the owner, operator, or agent in charge of a facility validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. Proposed § 117.150(a) would implement section 418(f)(1) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines describe verification as activities that, in relevant part, determine the validity of the HACCP plan (Ref. 34). The NACMCF guidelines advise that an important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that, if the HACCP plan is properly implemented, these hazards will be effectively controlled (Ref. 34). The Codex HACCP guidelines recommend that, where possible, validation activities include actions to confirm the efficacy of all elements of the HACCP system (Ref. 35). Our HACCP regulation for seafood does not specifically use the term ''validation,''

but it reflects the concept in requiring that every processor verify that the HACCP plan is adequate to control the hazards (§ 123.8(a)). Our HACCP regulation for juice addresses both validation of the HACCP plan (§ 120.11(b)) and the hazard analysis (§ 120.11(c)). The regulation requires each processor to validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur at least once within 12 months after implementation and at least annually thereafter. (This annual validation is the same as reanalysis proposed in § 117.150(f) and discussed in section XII.G.7 of this document. The requirement for validation of the hazard analysis in § 120.11(c) aligns more with a requirement for reanalysis and is discussed in section XII.G.2.a of this document). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that every establishment validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis. The regulations and guidelines described above reflect the widespread recognition of the importance of ensuring that preventive controls, if properly implemented, will adequately control the hazards.

b. Proposed § 117.150(a)(1)—Validation by a qualified individual prior to implementation and on reanalysis. Proposed § 117.150(a)(1) would require that the validation of the preventive controls be performed by (or overseen by) a qualified individual. The preventive controls must be adequate to control the hazards identified in the hazard analysis as reasonably likely to occur. Determining whether specific preventive controls are adequate requires an individual who is knowledgeable in the hazards associated with a product and process and the appropriate preventive controls for those hazards. Such knowledge requires scientific and technical expertise developed through training, experience or both.

Proposed § 117.150(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The validation of preventive controls includes collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 117.150(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first six weeks of production. We selected six weeks as a time interval that would be adequate to allow facilities to methodically collect data and information during production, yet would be close to implementation of a preventive control.

The NACMCF HACCP guidelines recommend that initial validation be conducted prior to and during initial implementation of the plan (Ref. 34). A Codex document entitled ''Guidelines for the Validation of Food Safety Control Measures'' (hereinafter the Codex validation guidelines) recommends that validation of control measures be performed, whenever possible, before their full implementation (Ref. 127). Codex also includes as a validation measure the collection of data, e.g., product and/or environmental sampling and testing, during operating conditions in the food operation for a specified period (e.g., 3–6 weeks) (Ref. 127). The HACCP regulation for juice requires that validation of HACCP plans be conducted once during the year after implementation and at least annually thereafter (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry (9 CFR 417.4(a)) requires that initial validation be conducted upon completion of the hazard analysis and development of the HACCP plan to determine that the HACCP plan is functioning as intended (9 CFR 417.4(a)(1)). During the HACCP plan validation period, the meat or poultry establishment must repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan (9 CFR 417.4(a)(1)).

FDA requests comment on whether the proposed time frame for validation should be shorter or longer. Comments should provide the basis for an alternative time frame.

Proposed § 117.150(a)(1)(ii) would require that the validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. The circumstances under which a reanalysis would be required are addressed in proposed § 117.150(f). Proposed § 117.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative, or, when necessary, during the first six weeks of production. All preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis; establishing that scientific and technical basis is a validation activity regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

c. Proposed § 117.150(a)(2)—Validation based on scientific and technical information. Proposed § 117.150(a)(2) would require that, except as provided by paragraph (a)(3) of this section, the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur. The NACMCF HACCP guidelines note that information needed to validate the HACCP plan often includes (1) expert advice and scientific studies and (2) in-plant observations, measurements and evaluations (Ref. 34). The Codex validation guidelines address several approaches for validating control measures, including (1) reference to scientific or technical literature, previous validation studies or historical knowledge, (2) scientifically valid experimental data, (3) collection of data during operating conditions, (4) mathematical modeling, and (5) surveys, and note that these may be used individually or in combination (Ref. 127).

The scientific and technical information that would be evaluated to determine whether preventive controls effectively control the hazards that are

reasonably likely to occur may include scientific publications, government documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers, trade associations, and other sources. If the qualified individual conducting the validation relies on sources such as scientific publications, the qualified individual would need to ensure during validation that the conditions used by the facility are consistent with those described in the publication that is being used to support the adequacy of the preventive control measure to control the hazard. For example, if a study demonstrates adequate inactivation of *Salmonella* spp. in peanuts using a roasting process, conditions such as roaster temperature, heating time, bed depth and humidity that were critical to achieving inactivation in the study must be the same when the facility roasts peanuts (or any change in the critical parameters must be such that the same or greater lethality is achieved). Documents published by FDA, such as the Food Code (Ref. 174), the Pasteurized Milk Ordinance (Ref. 37), and the Fish and Fisheries Products Hazards and Controls Guidance (Ref. 173) may provide scientific and technical information useful in establishing the validity of a preventive control measure, such as times and temperatures for cooling foods in which bacterial pathogen growth may occur or minimum water activities, minimum pH values, and minimum and maximum temperatures for growth of a variety of pathogens.

Predictive mathematical models that describe the growth, survival, or inactivation of microorganisms in foods may provide scientific and technical information useful in determining whether a process would be adequate to reduce microorganisms of public health concern (Ref. 34) (Ref. 127). Other risk-based models may examine the impact of a control measure on a hazard and may be useful if appropriately validated for a specific food. If the model is for a different food, it may still provide useful validation information that could be supplemented by additional data. For example, there are many mathematical models for thermal resistance of *Salmonella* spp. If a model for the thermal resistance of *Salmonella* spp. is developed for the same type of food as the food being produced, and the food being produced has the same critical parameters such as pH and a_w that were used in developing the thermal resistance model, then heat processes based on the model would generally be considered validated. For example, if a model for the thermal resistance of *Salmonella* spp. is developed in tomatoes with a pH of 4.3, the model would be considered valid for tomatoes with a pH of 4.3 or below, but not for tomatoes with a higher pH. If, however, the model is for thermal resistance of *Salmonella* spp. in a type of food that is only similar to the food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional thermal resistance studies in the food being produced to provide the data needed to show that a heat process adequately reduces *Salmonella* spp. in that food and to establish the critical parameters for the process. For example, a model for thermal resistance of *Salmonella* spp. on almonds may not apply to hazelnuts, even though the foods are similar in that both are tree nuts. The extent of such studies would, however, be less than the extent of such studies if there were no data on the heat resistance of *Salmonella* spp. in a similar food. For example, if the thermal resistance of *Salmonella* spp. in initial studies with hazelnuts is similar to that for almonds, then a thermal resistance study used to develop data for hazelnuts could investigate fewer times and temperatures, or use fewer replicates, than would be the case in the absence of the information about the thermal resistance of *Salmonella* spp. in almonds.

A process validation study would establish the relationship between parameters such as process times and temperatures and other factors and the rate at which pathogens are reduced, and a prevalence study would determine the levels at which pathogens may occur in the raw material, ingredient, or food product to establish the cumulative amount of pathogen reduction that would be required to adequately reduce the risk of illness from that pathogen. Such studies are typically published or otherwise broadly disseminated within the scientific community and, when properly designed and carried out, are generally regarded by experts as scientifically definitive with respect to the matters addressed by the study. However, if scientific and technical information is not available or is insufficient to support the adequacy of a preventive control measure to control the hazard, the owner, operator or agent in charge of a facility would need to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard. As an example, a facility that wants to use propylene oxide (PPO) to inactivate enteric pathogens such as *E. coli* O157:H7 on shelled hazelnuts would need to conduct studies to establish that PPO could significantly minimize the hazard because no such studies currently exist in the public domain. Such studies would also establish the critical parameters and limits (e.g., critical limits at a CCP) that the facility would need to use to effectively control the hazard. For the hazelnut example, the critical factors might include amount of PPO, temperature of the nuts to be treated, treatment time, chamber temperature, PPO vaporizer temperature, chamber vacuum, and post-treatment hold time and temperature. Studies on inactivation of *Salmonella* spp. on almonds could provide information about appropriate parameters to investigate for the inactivation of *E. coli* O157:H7 on shelled hazelnuts, but additional studies would be needed to establish the specific values for those parameters in the inactivation of *E. coli* O157:H7 on shelled hazelnuts.

Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. For example, NACMCF has published information on ''Parameters for Determining Inoculated Pack/Challenge Study Protocols'' (Ref. 175) and ''Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization'' (Ref. 176). Studies to validate preventive control measures must be conducted by persons with experience and expertise relevant to the product, process and hazard to be controlled. Under proposed § 117.150(a)(1)), any studies needed to provide the scientific and technical information to establish the validity of the plan would either be conducted by a qualified individual (as would be defined in proposed § 117.3) or would be overseen by a qualified individual. In other words, the qualified individual need not have the experience and expertise to conduct validation studies, but must have sufficient expertise in risk-based preventive controls to understand the studies and how they support the validity of the preventive controls with respect to the hazard of concern.

d. *Proposed § 117.150(a)(3)—Preventive controls for which validation is not required.* Proposed § 117.150(a)(3)(i) through (iii) would provide that validation need not address:

- The food allergen controls that would be established in proposed § 117.135(d)(2);
- The sanitation controls that would be established in proposed § 117.135(d)(3); and
- The recall plan that would be established in proposed § 117.137.

According to NACMCF, verification involves activities to determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. 34). Thus, validation is a verification activity. The purpose of validation is to provide the scientific and technical basis for ensuring that the preventive controls implemented are adequate to control the hazards identified as reasonably likely to occur. FDA tentatively concludes that validation, i.e., the evaluation of scientific and technical information, is either not an essential activity, is not practical or is not relevant, for the controls identified in proposed § 117.150(a)(3).

Food Allergen Controls

As discussed in section XII.C.6 of this document, proposed § 117.135(d)(2)(i) would require that food allergen controls include those procedures, practices, and processes employed for ensuring protection of food from cross-contact, including during storage and use. Examples of such procedures, practices, and processes include providing physical barriers between sections of a facility, conducting manufacturing/processing of foods in different parts of a facility, and controlling the movement of tools and personnel that might carry allergens when the same production lines are used for both foods that contain allergens and foods those that do not, or when the same production lines are used for foods that contain different allergens. These types of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 117.150(a)(2). Instead, monitoring (e.g., by visual observation) that these activities do not result in cross-contact provides sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to cross-contact. Examples of such visual observations include observations that bags of allergenic foods (such as soy flour) are stored in sealed containers, that spills of allergen powders are promptly cleaned, and that equipment is cleaned between manufacturing/processing of different foods. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen cross-contact controls that would be established in proposed § 117.135(d)(2)(i). We request comment on this approach.

As discussed in section XII.C.6 of this document, proposed § 117.135(d)(2)(ii) would require that food allergen controls include those procedures, practices, and processes employed for labeling the finished food, including, including ensuring that foods are not misbranded under section 403(w) of the FD&C Act. Examples of such procedures, processes, and practices include ensuring that the food label correctly declares all of the food allergens present (including those contained in flavorings, colorings, and incidental additives), ensuring that the correct food label is applied to a food, and ensuring that the correct food is in the correct package (e.g., by checking that the correct packaging is used for each food). These types of controls generally are not evaluated through scientific studies or by the collection of technical information as would be required under proposed § 117.150(a)(2). Instead, verifying that labels contain appropriate information and monitoring that the correct label is being applied to the product provide sufficient assurance that the controls are functioning as intended to prevent the hazard of undeclared allergens in the food due to incorrect labels. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the food allergen labeling controls that would be required by proposed § 117.135(d)(2)(ii). We request comment on this approach.

Sanitation Controls

As discussed in section XII.C.7 of this document, proposed § 117.135(d)(3)(i)(A) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. Traditionally, sanitarians employed by the facility or experts employed by companies that supply cleaning and sanitizing compounds will establish critical parameters and associated limits for cleaning and sanitation, including the choice and strength of the cleaning and sanitizing chemicals, contact time, and temperature requirements, based on studies conducted by the manufacturers of the products. Antimicrobial solutions applied to food processing equipment and utensils to sanitize such objects after they have been washed are included in the definition of ''pesticide chemical'' and therefore, are subject to regulation by EPA under section 408 of the FD&C Act (Ref. 118). Chapter 4 (Additional Considerations for Antimicrobial Products) of EPA's ''Pesticide Registration Manual'' (Ref. 177) outlines EPA's requirements and recommendations for registration of antimicrobial substances, including testing against a validated protocol to be granted EPA-registered claims for pathogen reduction. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the sanitation controls that would be required by proposed § 117.135(d)(3)(i)(A). Monitoring activities to ensure the procedures are followed will provide assurance that the controls are functioning as intended to prevent hazards from insanitary food-contact surfaces. We request comment on this approach.

As discussed in section XII.C.7 of this document, proposed § 117.135(d)(3)(i)(B) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the prevention of cross-contact and cross-contamination from insanitary objects and from employees to food, food packaging material, and other food-contact surfaces and from raw product to processed product. As already discussed with respect to proposed § 117.135(d)(3)(i)(A), sanitation controls to prevent cross-contamination can be established by sanitarians or by companies that supply cleaning and sanitizing compounds without the need for validation by the facility. Cleaning procedures established by sanitation experts should also be adequate to remove allergens from equipment and the environment in facilities where raw materials or ingredients containing allergens are used. Although it is prudent to validate the efficacy of cleaning with respect to allergens, appropriate allergen test methods may not be available at present for this purpose in all situations (Ref. 124). For example, when the same equipment is used to make milk-based and soy-based beverages, the availability of analytical methods that can detect milk protein and soy protein may make it practical to clean the equipment and then test a water rinse of the system to determine whether milk or soy proteins can be detected in the rinse water. However, this may not be the case when equipment used to make breaded shrimp is subsequently used to make breaded fish. We tentatively conclude

that validation by the facility to demonstrate that sanitation controls adequately protect against cross-contact is not feasible for all situations at this time.

Regardless of whether this proposed rule would require the specific verification activity of validation to demonstrate that sanitation controls adequately protect against cross-contact, proposed § 117.135(d)(3)(i)(A) would require that the owner, operator, or agent in charge of a facility establish appropriate allergen sanitation procedures to ensure that products do not contain undeclared allergens from other products. Cleaning procedures established to remove food residues and verification that food residues have been removed (e.g., by visual inspection) should significantly minimize or prevent the presence of undeclared food allergens. When appropriate tests are available, we recommend that facilities use testing as well as visual inspection to verify that procedures have been done adequately. We request comment on this approach. We also request comment on whether we should require validation of sanitation controls to protect against cross-contact in those situations where appropriate analytical methods for use in validation studies are currently available, even if such methods are not available for all major food allergens.

Recall Plan

As discussed in section XII.C.8 of this document, a recall plan can significantly minimize or prevent hazards by limiting consumption of affected food during a recall. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies simply does not apply to such a plan. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the recall plan that would be required by proposed § 117.137.

3. Proposed § 117.150(b)—Verification of Monitoring

Proposed § 117.150(b) would require that the owner, operator, or agent in charge of a facility verify that monitoring is being conducted, as would be required by proposed § 117.140. One example of verification that monitoring is being conducted is a periodic observation of the monitoring activity, e.g., by a supervisor. Another example of such a verification activity is an independent test made by a person other than the person doing the monitoring. For example, if the line operator is verifying the operation of a metal detector by running test pieces through the metal detector every two hours to verify it rejects them, a quality assurance technician could periodically run a similar test—e.g., once per shift. Proposed § 117.150(b) does not address the review of monitoring records, which would be required under proposed § 117.150(d)(2)(i) (see the discussion in section XII.G.5.b of this document).

Proposed § 117.150(b) would implement section 418(f)(2) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which requires direct observations of monitoring activities as an ongoing verification activity (9 CFR 417.4(a)(2)(ii)). Proposed § 117.150(b) would differ from the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP guidelines (Ref. 35), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(i) and 120.11(a)(1)(iv)(A), respectively), which address verification of monitoring through the review of records (which would be required by proposed § 117.150(d)(2)(i)) but do not otherwise address verification activities for monitoring.

Proposed § 117.150(b) would not specify the verification activities that must be conducted for monitoring. We request comment on whether proposed § 117.150(b) should do so, and if so, what verification activities should be required.

4. Proposed § 117.150(c)—Verification of Corrective Actions

Proposed § 117.150(c) would require that the owner, operator, or agent in charge of a facility verify that appropriate decisions about corrective actions are being made, as would be required by proposed § 117.145 and by proposed § 117.135(d)(3)(ii). An example of verification that appropriate decisions about corrective actions are being made is observation of the corrective actions being taken, e.g., by a supervisor. Proposed § 117.150(c) would implement section 418(f)(3) of the FD&C Act and is consistent with the FSIS HACCP regulation for meat and poultry, which includes direct observations of corrective actions as an ongoing verification activity (9 CFR 417.4(2)(ii)). Proposed § 117.150(c) would differ from the NACMCF HACCP guidelines (Ref. 34), the Codex HACCP guidelines (Ref. 35), and FDA's HACCP regulations for seafood and juice (§§ 123.8(a)(3)(ii) and 120.11(a)(1)(iv)(B), respectively), which address verification of corrective actions through the review of records (which would be required by proposed § 117.150(d)(2)(i)) but do not otherwise address verification activities for corrective actions.

Proposed § 117.150(c) would not specify the verification activities that must be conducted for corrective actions. We request comment on whether proposed § 117.150(c) should do so, and if so, what verification activities should be required.

5. Proposed § 117.150(d)—Implementation and Effectiveness

Proposed § 117.150(d) would require that the owner, operator, or agent in charge of a facility verify the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the requirements in proposed § 117.150(d)(1) and (2), as appropriate to the facility and the food. Proposed § 117.150(d) would implement section 418(f)(4) of the FD&C Act, which requires in relevant part verification by ''appropriate means'' that the preventive controls ''are effectively and significantly minimizing or preventing the occurrence of identified hazards.''

a. Proposed § 117.150(d)(1)—Calibration. Proposed § 117.150(d)(1) would require calibration of process monitoring instruments and verification instruments. As discussed in section II.D.3 of this document, the combination of monitoring (proposed § 117.140(a)), recordkeeping (proposed § 117.175), and verification (proposed § 117.150(a) and (d)) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act would be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility would not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. In many instances, monitoring and verification activities rely on instruments (such as a pH meter or a thermometer) that must be calibrated. Calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance that hazards will be significantly minimized or prevented. If an instrument is calibrated against a known reference, the reference standard may also need periodic calibration (e.g., the standard reference thermometer used to calibrate a thermometer used in processing

equipment will itself also need to be calibrated periodically).

Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 117.150(d)(1) would not specify a frequency for calibration.

b. Proposed § 117.150(d)(2)—Records review. Proposed § 117.150(d)(2) would require a review of specific records related to monitoring, corrective actions and certain verification activities within specified time frames, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. Proposed § 117.150(d)(2)(i) would require review of the monitoring and corrective action records within a week after the records are made. Proposed § 117.150(d)(2)(ii) would require review of the records related to calibration within a reasonable time after the records are made. (As discussed in section XII.I.2 of this document, proposed § 117.175 would list the records that facilities must establish and maintain, including records that document the monitoring of preventive controls as required by § 117.140(c), corrective actions as required by § 117.140(d), and verification activities as required by § 117.150(g)).

Proposed § 117.150(d)(2) would implement section 418(f) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines provide examples of verification activities, including review of the HACCP plan for completeness, review of monitoring records, and review of records for deviations and corrective actions (Ref. 34). The examples of verification activities in the Codex HACCP Annex include a review of the HACCP plan and its records (Ref. 35). Our HACCP regulations for seafood (§ 123.8(a)(3)(i) through (iii)) and juice (§ 120.11(a)(1)(iv)(A) through (C)) require a review of the records that document the monitoring of critical control points, the taking of corrective actions, the calibrating of any process control instruments used at critical control points, and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The FSIS HACCP regulation for meat and poultry requires a review of all required records (9 CFR 417(a)(2)(iii)).

Proposed § 117.150(d)(2) would establish that the purpose of the review of records would be to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decision were made about corrective actions. We tentatively conclude that review of the records required by proposed § 117.150(d)(2)(i) and (ii) would accomplish these purposes. Reviewing monitoring records can reveal whether they contain information on all the parameters that were to be monitored to determine whether a process is delivered in accordance with the food safety plan. For example, if both the size of food particles to be acidified and the pH of the food after acidification are critical to the safety of the food, review of the monitoring records would demonstrate whether both particle size and pH were monitored and whether the values were within specified parameter values. Reviewing monitoring records can reveal whether a process followed the procedures specified in the facility's food safety plan (e.g., if the monitoring records show the pH of every other batch of an acidified food when the plan specified the measurement of every batch). Review of monitoring records also can reveal whether any information is missing—e.g., a designated lot number—so that the missing information can be quickly identified and added to the record if necessary. We seek comment on this proposal.

If the review of the records reveals that the records do not contain all information specified by the food safety plan, or that the procedure in the food safety plan was not followed, the facility will not be able to conclude that its preventive controls were implemented in accordance with its food safety plan for those activities. Because the food safety plan establishes the procedures needed to ensure preventive controls are effective, if the records review indicates that the plan is not being followed, e.g., the records are missing critical information or the activities were not performed as specified in the plan, the facility will not be able to conclude its preventive controls were effective. For example, if the records show that food particle size is not being determined or that the particles are too large, acidification of all parts of the particle may not occur rapidly enough to ensure control of pathogens such as *C. botulinum.* If the plan requires determination of the pH of each batch of product but the records do not show that the pH was measured on all batches, the facility cannot be sure that the pH of those batches is correct, again posing a potential risk from *C. botulinum.* As a result, the facility would not be able to verify that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

Review of records can also reveal whether appropriate decisions were made about corrective actions. The review should determine whether all the corrective action procedures required by proposed § 117.145(a)(3) have been followed, e.g., that actions are taken to prevent recurrence of the problem, that affected food has been evaluated for safety, and that affected food is prevented from entering commerce unless it can be determined that the food is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. For example, a food safety plan may require that each package of product pass through a properly functioning metal detector and that the operator determine every two hours whether metal test pieces of a specified type and size are rejected when passed through the metal detector. If one of the test pieces was not rejected but production continued until a supervisor doing a verification check noted the problem, then corrective actions should have been taken and a corrective action record produced. A review of the corrective action records should reveal that all packages of product that passed through the metal detector since the last test showing the metal detector was functioning appropriately were held and passed through a functioning metal detector before being released into commerce. The records should also show that the metal detector was adjusted to reject the metal test pieces before it was used again to check product during production.

Proposed § 117.150(d)(2) would require that the review of records be performed by (or under the oversight of) a qualified individual (see the discussion in section XII.H of this document regarding the activities that must be performed (or overseen) by a qualified individual as would be established in proposed § 117.155). The review of records is critical to assessing

the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation. Our HACCP regulations for seafood (§ 123.8(a)(3)) and juice (§ 120.11(a)(1)(iv)) require that the review of records be conducted by an individual who has successfully completed training in the application of HACCP principles to the processing of the applicable food product at least equivalent to that received under standardized curriculum recognized as adequate by FDA, or who is otherwise qualified through job experience to perform this function. The FSIS HACCP regulation for meat and poultry requires that records be reviewed, ''preferably'' by an individual trained by successfully completing a course of instruction in the application of the HACCP principles to meat or poultry product processing (9 CFR 417.5(c) and 417.7(b)). The NACMCF HACCP guidelines stress the role of qualified experts in the development and evaluation of a HACCP plan, and recommend periodic comprehensive verification of the HACCP system by an unbiased, independent authority, internal or external to the food operation, including review of appropriate records from operation of the plan (Ref. 34). The Codex HACCP Annex does not specifically address the need for a qualified individual to review the records other than to recommend that where certain verification activities cannot be performed in-house, verification be performed on behalf of the business by external experts or qualified third parties (Ref. 35).

Proposed § 117.150(d)(2)(i) would require review of the monitoring and corrective action records within a week after the records are made. Although proposed § 117.150(d)(2)(i) would establish a more frequent review of these records than recommended in the NACMCF guidelines (which recommend monthly verification of monitoring records and corrective action records), it is consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(i) and (ii)) and juice (§ 120.11(a)(1)(iv)(A) and (B)), which require that the review of monitoring records and corrective action records occur within one week of the day that the records are made. Even for shelf-stable foods (e.g., low-acid canned foods and acidified foods) our experience has demonstrated that review of these kinds of records is a critical verification tool (60 FR 65096 at 65133). We seek comment on the proposed one week timeline. The FSIS HACCP regulation for meat and poultry requires records to be reviewed prior to shipping product (9 CFR 417.5(c). As discussed in the seafood HACCP final rule (60 FR 65096 at 65132), review of records needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a ''feedback loop,'' with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product. If a problem with product is discovered during a review of records, all product since the last review could be affected. Although verification prior to shipment provides a valuable added assurance, FDA explained in the preamble to the seafood HACCP final rule (60 FR 65096 at 65132) that with highly perishable products this is not always possible and that a weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records.

Proposed § 117.150(d)(2)(ii) would require review of the records related to calibration within a reasonable time after the records are made. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the calibrations would be reasonable. Consequently, FDA tentatively concludes that setting a specific frequency for review of these records is not warranted. Proposed § 117.150(d)(2)(ii) is, in relevant part, consistent with our HACCP regulations for seafood (§ 123.8(a)(3)(iii)) and juice (§ 120.11(a)(1)(iv)(C)), which require that the review of records of calibrating of any process control instruments used at critical control points occur within a reasonable time after the records are made.

As noted previously, proposed § 117.150(d)(2) would require a review of records in part to determine whether the preventive controls are effective. A review should determine whether monitoring and corrective actions have been done in accordance with the food safety plan and whether the instruments used in monitoring and verification were properly calibrated. If food safety activities appropriate to the facility have been conducted in accordance with the plan and this is reflected in the records, the facility thus verifies the preventive controls are effective, i.e., that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

6. Proposed § 117.150(e)—Written Procedures for Verification Activities

Proposed § 117.150(e) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments. We are proposing to require written procedures for the frequency of calibration because the frequency of calibration will vary depending on the instrument and the process or verification activity that it pertains to.

We are not proposing to require that written procedures be developed for all verification procedures. In some instances the records of verification activities provide the information needed to understand how the verification activity has been carried out and to assess whether the verification activity is adequately demonstrating that the preventive controls are effective in significantly minimizing or preventing the hazards reasonably likely to occur. For example, we are not proposing to require written procedures for validation, verification of monitoring and corrective actions, or calibration of process monitoring instruments and verification instruments (other than for the frequency of calibration). Validation involves a variety of procedures, including evaluation of scientific and technical information and conducting laboratory and in-plant studies that generally do not follow a standardized protocol or approach. Records of monitoring and corrective actions provide the information needed to understand how the verification activity was carried out. In many instances the calibration of process monitoring instruments and verification instruments will be done by contract with other entities and the facility would not have access to the procedures used; having instruments calibrated and documenting the calibration provides the necessary assurance that such instruments will be accurate. However, the frequency of calibration must be specified to ensure that the instruments are calibrated on a schedule appropriate to the instrument and the process it controls.

Section 418(f) of the FD&C Act establishes certain requirements for verification, and section 418(h) of the

FD&C Act requires that the procedures used by the facility to comply with the requirements of section 418 be included in the written plan. Our HACCP regulations for seafood and juice both require that the HACCP plan be written (§§ 123.6(b) and 120.8(a), respectively) and that procedures for verification be included in the written HACCP plan (§§ 123.6(c)(6) and 120.8(b)(6), respectively). The FSIS HACCP regulation for meat and poultry requires that the establishment maintain a record of the written HACCP plan, including, in relevant part, documents supporting the verification procedures selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Thus, requiring verification procedures to be written implements the requirements in section 418 of the FD&C Act and is consistent with the requirements in HACCP regulations for seafood, juice, and meat/poultry.

7. Proposed § 117.150(f)—Reanalysis

a. Proposed § 117.150(f)(1)—Reanalysis on the initiative of the owner, operator, or agent in charge of a facility. Proposed § 117.150(f)(1)(i) would require that the owner, operator, or agent in charge of a facility conduct a reanalysis of the food safety plan:

- At least once every 3 years (proposed § 117.150(f)(1)(i)(A));
- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard (proposed § 117.150(f)(1)(i)(B));
- Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food (proposed § 117.150(f)(1)(i)(C));
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established (proposed § 117.150(f)(1)(i)(D)); and
- Whenever a preventive control is found to be ineffective (proposed § 117.150(f)(1)(i)(E)).

For example, if a facility that bottles beverages develops a food safety plan for its products packaged in plastic bottles and subsequently introduces a glass bottling line, the facility would be required to reanalyze its food safety plan because the glass bottling line creates a reasonable potential for a new hazard, i.e., glass particles. Similarly, if a facility that conducts dry roasting operations for nuts makes design changes to its roasters to increase product throughput, the facility would be required to reanalyze its food safety plan because a design change to equipment that is used to control a hazard that is reasonably likely to occur would be a significant change in the activities conducted at the facility.

The owner, operator or agent in charge of a facility may become aware of a problem due to the finding of a hazard in a food as the result of testing by a regulatory agency (Federal, State, tribal, or foreign government) that would require an analysis of the food safety plan to ensure the hazard is significantly minimized or prevented by appropriate preventive controls. In addition, new hazards can emerge—e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. For example, *L. monocytogenes* was not recognized as a food safety hazard until a series of outbreaks of foodborne illness associated with the consumption of foods such as coleslaw and fresh soft cheese in the early 1980s (Ref. 178). As another example, in 2006–2007 there was an outbreak of salmonellosis due to contamination of peanut butter with *Salmonella* Tennessee (Ref. 63). This was the first outbreak of foodborne illness caused by peanut butter consumption in the U.S. and it demonstrated the need for manufacturers to address the hazard of *Salmonella* spp. in this product. Information about outbreaks and ensuing product recalls is widely disseminated, including on FDA's Web site, and modern communication tools make it possible for the owner, operator, or agent in charge of a facility to receive such information automatically. For additional discussion related to the proposed requirement that the owner, operator, or agent in charge of a facility conduct a reanalysis whenever such owner, operator or agent becomes aware of new information about potential hazards associated with the food, see the discussion in section XII.G.7 of this document of proposed § 117.150(f)(3), which would provide that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

As noted in section XII.F.3, proposed § 117.145(b)(2) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 117.150(f) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented or is found to be ineffective, and a specific corrective action has not been established. If the owner, operator, or agent in charge of a facility has not identified a specific failure as a foreseeable occurrence, the deviation may be the result of a system-wide problem that is not being properly addressed by the food safety plan (e.g., ineffective preventive controls). Thus, an unforeseen failure for which a corrective action was not identified may indicate an ineffective preventive control, and a reanalysis of the food safety plan is warranted. Similarly, when information arises indicating that the preventive control has not been effective in significantly minimizing or preventing a hazard from occurring, a reanalysis must be conducted to determine if the food safety plan should be modified to ensure that the preventive controls implemented are adequate to significantly minimize or prevent a hazard identified as reasonably likely to occur.

Proposed § 117.150(f)(1)(i) would implement sections 418(f)(5) and 418(i) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, the Codex validation guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. FDA notes that the terminology used in relation to the concept of ''reanalysis'' varies in the regulations and guidelines (e.g., ''subsequent validation,'' ''re-validation,'' ''reassessment of the hazard analysis,'' and ''validation'' of the HACCP plan). The NACMCF HACCP guidelines include validation of a HACCP plan to ensure that the plan is scientifically and technically sound and that all hazards have been identified as an important verification activity, and advise a subsequent validation under circumstances such as an unexplained system failure; a significant product, process or packaging change; or the recognition of new hazards (Ref. 34). The NACMCF HACCP guidelines also discuss the need for a periodic comprehensive verification of the HACCP system, including a technical evaluation of the hazard analysis and each element of the HACCP plan, independent of other verification procedures to ensure that the HACCP plan is resulting in control of the hazards. If the results of the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary (Ref. 34). Likewise, the Codex HACCP Annex recommends that the HACCP application be reviewed and necessary changes made when any modification is made in the product, process, or any step (Ref. 35). The Codex validation guidelines provide examples of situations that could lead to the need to

re-validate a control measure or combination of control measures, e.g., system failure, process changes, and new scientific or regulatory information (Ref. 127).

Our HACCP regulation for seafood requires a reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way, or at least annually (§ 123.8(a)(1)). Our HACCP regulation for juice requires an initial validation within 12 months after implementation and at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way (§ 120.11(b)). The FSIS HACCP regulation for meat and poultry requires that every establishment reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)).

In addition, Federal HACCP regulations for seafood, juice, and meat and poultry require a reassessment of the hazard analysis when a processor does not have a HACCP plan (because the hazard analysis revealed no hazards reasonably likely to occur) and there are changes that could affect whether a food safety hazard now exists (§§ 123.8(c) and 120.11(c), and 9 CFR 417.4(a)(4) for seafood, juice, and meat and poultry, respectively). Each of these HACCP regulations provides examples of changes that may be considered to reasonably affect whether a food safety hazard now exists and, thus, require reassessment of the adequacy of the hazard analysis (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(4)). Such changes include changes in raw materials or the source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; the intended use or consumers of the finished product; and slaughter or processing methods or systems for meat or poultry.

The requirement in proposed § 117.150(f)(1)(i)(A) that the periodic reanalysis of the food safety plan occur at least once every 3 years would be different from the current requirement in our HACCP regulations for seafood and juice and in the FSIS HACCP regulation for meat and poultry for reassessment (validation) of the adequacy of the HACCP plan to be done ''at least annually'' (§§ 123.8(a)(1) and 120.11(b) and 9 CFR 417.4(a)(3), respectively). The 3-year minimum frequency for the periodic reanalysis of the food safety plan is explicitly required by section 418(i) of the FD&C Act. We tentatively conclude that, as a practical matter, the proposed requirement for reanalysis whenever a significant change is made in the activities conducted at a facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard makes it likely that reanalysis would occur more frequently than every 3 years because such changes are likely to occur more frequently than every 3 years.

Proposed § 117.150(f)(1)(ii) would require that the owner, operator, or agent in charge of a facility complete the required reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. The purpose of the reanalysis is to identify the need for, and implement, preventive controls in light of a reasonable potential for a new hazard, or a significant increase in a previously identified hazard, that is reasonably likely to occur. It follows that the preventive controls must be in place before making the change that creates the potential for a new hazard or a significant increase in a previously identified hazard. As with initial validation in proposed § 117.150(a)(1)(i), we are proposing to provide the first six weeks of production, when necessary, to implement any additional preventive controls to allow facilities to methodically collect data and information during production to ensure the needed change can be implemented in the facility. We seek comment on this timeframe. Proposed § 117.150(f)(1)(ii) would implement section 418(i) of the FD&C Act. Although proposed § 117.150(f)(1)(ii) has no explicit counterpart in the NACMCF HACCP guidelines, the Codex HACCP guidelines, or Federal HACCP regulations for seafood, juice, and meat and poultry, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations and with requirements to modify the HACCP plan immediately whenever validation reveals the need to do so, as discussed immediately below.

Proposed § 117.150(f)(1)(iii) would require that the owner, operator, or agent in charge of a facility revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. Proposed § 117.150(f)(1)(iii) would implement section 418(i) of the FD&C Act, which requires that the written plan be revised ''if * * * a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.'' As discussed in section XII.B.2.b of this document, the written hazard analysis is required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur. It is also important to document that a reanalysis has been conducted even if no change has been made, as required by section 418(i) of the FD&C Act. Such documentation demonstrates that a facility has considered all relevant information on the safety of the products being produced, including new information that has become available since the last analysis, and determined that current procedures for implementing preventive controls are adequate to significantly minimize or prevent hazards that are reasonably likely to occur. Our HACCP regulations for juice and seafood, and the FSIS regulation for meat and poultry, require that the HACCP plan be modified immediately whenever a validation/reassessment reveals that the plan is no longer adequate to fully meet the requirements of the HACCP regulations (§§ 120.11(b) and 123.8(a)(1) and 9 CFR 417.4(a)(3) for juice, seafood, and meat/poultry, respectively), although they do not explicitly require documentation of the basis for the conclusion that no additional or revised preventive controls are needed. Although proposed § 117.150(f)(1)(iii) has no explicit counterpart in the NACMCF HACCP guidelines or the Codex HACCP guidelines, it is consistent with the importance placed on reanalysis of the HACCP plans in those guidelines and regulations, and with the written nature of the HACCP plan. The Codex validation guidelines indicate that if a system failure for which a process deviation cause cannot be identified occurs, re-validation may be needed (i.e., reanalysis is needed whenever a preventive control is found to be ineffective) (Ref. 127).

b. Proposed § 117.150(f)(2)—Requirement for a qualified individual. Proposed § 117.150(f)(2) would require that the reanalysis be performed or overseen by a qualified individual. Proposed § 117.150(f)(2) is consistent with proposed §§ 117.126(c) which would require that the food safety plan be developed or overseen by a qualified individual. We tentatively conclude that the same qualifications are needed whether initially conducting a hazard analysis and establishing a food safety plan, or reanalyzing a hazard analysis and plan.

c. Proposed § 117.150(f)(3)—Reanalysis on the initiative of FDA. Proposed § 117.150(f)(3) establishes that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding. This authority will be delegated to the Commissioner of Food and Drugs. Proposed § 117.150(f)(2) would implement section 418(i) of the FD&C Act, which provides in relevant part that ''[t]he Secretary may require a reanalysis * * * to respond to new hazards and developments in scientific understanding * * * .'' As discussed in section XII.G.7.a of this document, new hazards can emerge—e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. In addition, new developments can occur in the scientific understanding of existing or potential hazards—e.g., if scientists and food safety regulatory agencies develop a better understanding of the causes of these events. For example, the outbreak from *Salmonella* Tennessee in peanut butter resulted in a greater understanding of the risks posed by environmental contamination and the importance of control of water in facilities producing low-moisture foods (Ref. 145) (Ref. 179). Information submitted to the RFR—which is a relatively recent addition to the regulatory framework for food safety—has the potential to identify new hazards or routes of contamination even before outbreaks occur. For example, the January 2011 RFR Annual Report (Ref. 60) identified a high number of primary reports involving *Salmonella* spp. in spices and seasonings, and we have requested comments and scientific data and information to assist us in our plans to conduct a risk profile for pathogens and filth in spices (75 FR 20615, April 20, 2010). The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices.

8. Proposed § 117.150(g)—Requirement for Records for Verification

Proposed § 117.150(g) would require that all verification activities taken in accordance with this section be documented in records. Proposed § 117.150(g) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan and includes verification records as an example of HACCP records in an appendix (Ref. 34). The Codex HACCP Annex gives records of verification procedures performed as an example of records (Ref. 35). Our HACCP regulations for seafood and juice require that recordkeeping include the calibration of process-monitoring instruments (§§ 123.8(d) and 120.11(a)(2), respectively). The FSIS HACCP regulation for meat and poultry requires records documenting the calibration of process-monitoring instruments, as well as verification procedures and results.

H. Proposed § 117.155—Requirements Applicable to a Qualified Individual

Proposed § 117.155(a) would require that one or more qualified individuals prepare the food safety plan (proposed § 117.126(c)), validate the preventive controls (proposed § 117.150(a)(1)), review records for implementation and effectiveness of preventive controls (proposed § 117.150(d)(2)), and perform reanalysis of the food safety plan (proposed § 117.150(f)(2)). We have discussed the basis for requiring that a trained individual perform or oversee these functions in our discussion of each applicable proposed provision. We are listing the functions that must be performed by a trained individual in § 117.155(a) for simplicity and are not imposing any additional requirement through this list. A single individual with appropriate qualifications could perform all of the listed functions, but there would be no requirement for the same individual to perform all the listed functions.

Proposed § 117.155(b) would establish the qualification requirements applicable to a qualified individual. To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Training or job experience is essential to the effective development and implementation of a hazard analysis and risk-based preventive controls. Only a trained individual or individual qualified by job experience is capable of effectively executing certain activities, such as identifying hazards that are reasonably likely to occur; identifying preventive controls that will address those hazards; evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur; determining the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; determining whether monitoring procedures and corrective action procedures are appropriate; and determining whether specific corrective actions have been appropriate and effective. In addition, the products produced by the food industry are diverse, and the hazards that are reasonably likely to occur in a particular facility depend on a range of factors that vary from one facility to the next. We seek comment on the scope of the qualifications identified.

Proposed § 117.155 is consistent with the NACMCF HACCP guidelines, our HACCP regulations for seafood and juice, and USDA's HACCP regulations for meat and poultry. The NACMCF HACCP guidelines recommend that experts who are knowledgeable in the food process either participate in or verify the completeness of the HACCP plan (Ref. 34). Our HACCP regulations for seafood and juice both require that only a trained individual be responsible for developing the hazard analysis (juice only), developing the HACCP plan, verifying and modifying the HACCP plan, and performing the record review (§§ 123.10(a)–(c) and 120.13(a)(1)–(4), respectively). These regulations also provide that job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. USDA's HACCP regulations for meat and poultry require that only an individual who has completed a training course can conduct certain activities, such as development and modification of the HACCP plan (9 CFR § 417.7).

FDA did not conduct HACCP training for persons subject to our HACCP regulations for seafood or juice. However, when implementing those regulations, FDA worked with an alliance of representatives from Federal and State agencies, industry and academia, to create a uniform, core training program that serves as the standardized curriculum against which other course materials can be judged. FDA will be working with an alliance to develop such a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls. Having a

standardized curriculum on which facilities, as well as private organizations and academia that conduct training, can base their materials and training would provide a framework to ensure minimum training requirements are met.

Proposed § 117.155(b) also would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. Proposed § 117.155(b) is consistent with HACCP regulations for seafood and juice, which have virtually identical requirements (§§ 123.10 and 120.13(b), respectively). The option in proposed § 117.155(b) would provide flexibility to facilities subject to the rule. Such flexibility may be particularly important for those facilities that have limited technical expertise.

Proposed § 117.155(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. Such records would be a simple mechanism to demonstrate that a person has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, as would be required under proposed § 117.155(b) should the qualified individual not be otherwise qualified through job experience to develop and apply a food safety system.

I. Proposed § 117.175—Records Required for Subpart C

1. Requirements of Section 418 of the FD&C Act

Section 418(g) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also specifies that the written plan, together with the documentation described in Section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 117.175—Records Required for Subpart C

Proposed § 117.175(a)(1) through (5) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:

- The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis; and
- Records that document applicable training for the qualified individual.

Proposed § 117.175(a) would not establish any new requirements but merely make it obvious at a glance what records are required under proposed part 117, subpart C.

Proposed § 117.175(b) would provide that the records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of part 117, subpart F. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by part 117, including provisions for retention of records and for making records available for official review.

J. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed

1. Overview

As discussed in section II.B.2 of this document, section 418(n) requires FDA to establish science-based minimum standards for, among other things, implementing preventive controls. In addition, section 418(f) requires certain verification of those preventive controls. In this section of the preamble, we discuss several preventive controls (i.e., supplier controls) and verification measures (i.e., environmental and product testing programs) that FDA is not including as provisions in proposed part 117, subpart C.

As we have already discussed (see section XII.C.1 of this document), section 418(c) requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls. Section 418(o)(3) defines ''preventive controls'' to mean ''those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding * * *.'' Section 418(o)(3) indicates that those procedures, practices and processes may include environmental monitoring, supplier verification activities, certain sanitation controls, and allergen controls. In addition, environmental and product testing programs are set out in section 418(f)(4): Section 418(f)(4) requires that the owner, operator, or agent in charge of a facility ''verify that * * * the preventive controls * * * are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.''

We believe that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system. We believe that the preventive controls discussed in this section (i.e., a supplier approval and verification program), when implemented appropriately in particular facilities, are ''risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding * * *'' The verification procedures discussed in this section (i.e., environmental and product testing programs), when implemented

appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. The use of and need for these preventive controls and verification measures, which are science-based, are widespread and commonly accepted in many sectors of the food industry. We request comment on these conclusions.

As discussed (see section I of this document), food safety is best assured if each facility understands the hazards that are reasonably likely to occur in its particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate those hazards. From a regulatory perspective, specifying the circumstances and manner in which these controls and practices are to be applied must take into account the wide array of factors, including the diversity among food products, the wide variety of manufacturing and processing methods used to produce the food, the variety of sources for raw materials and ingredients, variations in the nature and types of hazards associated with manufacturing, processing, packing and holding human food, and the possibility that different mitigation methods may achieve the same end. Further, regulatory requirements should make clear when one of these preventive controls or verification measures is necessary yet also be sufficiently flexible to account for a vast number of food and facility combinations and circumstances.

Although we are not including provisions for environmental and product testing programs or a supplier approval and verification program in this proposed rule, we recognize that these preventive controls and verification measures, when implemented appropriately in particular facilities, can play important roles in effective food safety programs. The role and need for these measures varies depending on the type of products and activities of the facility. To facilitate comment and share our current thinking, we discuss the topics of environmental and product testing programs and a supplier approval and verification program immediately below. See the Appendix to this document for additional background information relevant to these topics.

2. Product Testing

As discussed in section XII.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means'' The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to establish a product testing program.

Although finished product testing is rarely considered a preventive control, it plays a very important role as a verification measure in ensuring the safety of food, when implemented appropriately in particular facilities. Similarly, testing of raw materials or ingredients by a facility that is receiving the product often plays an important role in verification of hazard control that is performed by their supplier. Thus, an important purpose of testing is to verify that preventive controls, including those related to suppliers and those related to environmental monitoring, are controlling the hazard (Ref. 111) (Ref. 112). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan.

Finished product testing is more important and useful when there is a reasonable probability that exposure to an identified hazard will result in serious adverse health consequences or death to humans or animals. FDA believes that there are certain situations in which finished product testing is particularly useful as a verification measure, including the following circumstances:

- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur in an ingredient and the preventive controls established and implemented under proposed § 117.135 do not include a process control that will significantly minimize the hazard. Examples include cut raw vegetables (such as celery, onions, leafy greens and tomatoes) that may contain *Salmonella* spp. or *L. monocytogenes* and that are intended to be used in RTE foods; nutrition bars in which dry ingredients (such as fruits, nuts, dried milk, soy proteins and chocolate) that may contain *Salmonella* spp. are formed into a bar without a lethal step; and mixtures of shelled nuts in which the nuts may be contaminated with *Salmonella* spp.
- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur in an ingredient that is added during manufacturing after the stage that applies a process control to significantly minimize biological hazards. Examples include food (such as chips, nuts and cereals) in which untreated seasonings that may contain *Salmonella* spp. are applied after a heat treatment and food (such as ice cream) to which nuts or other ingredients are added to an ice cream mix that has been pasteurized.
- The outcome of the hazard analysis conducted under proposed § 117.130 is that a biological hazard is reasonably likely to occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. Examples include the manufacture of nut butters from roasted nuts (where contamination with *Salmonella* spp. from the environment is a concern); the mixing of dried, treated spices and herbs (where contamination with *Salmonella* spp. from the environment is a concern); the addition of herbs or vegetables to products such as cream cheese or cottage cheese (where contamination with *L. monocytogenes* from the environment is a concern); and the manual assembly of sandwiches (where contamination with *S. aureus, L. monocytogenes,* and enteric pathogens such as *Salmonella* spp. is a concern).

In addition, the frequency of testing and the number of samples tested must be determined and needs to take into account a variety of hazard/commodity/facility considerations. FDA believes that factors to consider include whether ingredients that may contain a hazard have been tested, the extent of any environmental monitoring program, and whether other programs established by the facility provide added assurance that the potential for hazards has been minimized. The frequency of testing and the number of samples tested should have a scientific basis. Sampling plans and their performance have been described in the literature (Ref. 180) (Ref. 181) (Ref. 182) and are included in several Codex documents (Ref. 52) (Ref. 183). We discuss likely considerations that could impact finished product

verification testing in more detail in section I.F of the Appendix to this document.

Although we are not including a testing provision in this proposed rule, we estimate that a requirement for a finished product testing program, when implemented appropriately in particular facilities, could impose an incremental annual cost of $14,000–$813,000 per facility based on size (number of employees) that adopts a testing and holding regime. This would result in an estimated aggregate cost of $23,500,000 for domestic facilities based on an average of a range of $12,000,000–$35,000,000 (assuming between 25 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $25,600,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.) These costs assume that facilities will take 5 finished product samples per product line on a monthly basis. The facilities that would adopt a testing and holding regime are facilities producing products for which finished product testing would be particularly useful as a verification measure, e.g., the production process does not have a step that will eliminate or reduce hazards to an acceptable level. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the ''Consideration of Other Provisions'' section of the PRIA.

FDA requests comment on when and how product testing programs are an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. Should a product testing program be limited to finished product testing or include raw material testing? What is the appropriate level of specificity for a product testing program? For example, should we simply require that the owner, operator, or agent in charge conduct, as appropriate to the facility and the food, finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur? This would provide flexibility to account for the wide diversity of food and food manufacturing, processing, packing and holding systems subject to this rule and be consistent with the discussions within this proposed rule.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying particular hazards, situations or product types for which finished product testing would be required;
- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product;
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control; and
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency.

FDA also requests comment on the impact of product testing requirements on small businesses and on whether any product testing verification requirements should differ based on the size of the operation.

3. Environmental Monitoring

As discussed in section XII.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means''. In addition, section 418(o)(3) indicates that preventive controls may include environmental monitoring to verify the effectiveness of pathogen controls is an example of preventive controls. The statute does not indicate the specific circumstances where environmental testing would be required or the specific manner in which such testing should be performed. Nevertheless, FDA believes that this testing can form an important component of a modern food safety system. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (i.e., sanitation controls) when contamination of food with an environmental pathogen is a hazard reasonably likely to occur.

As discussed in sections XII.B.3 and XII.B.4.b of this document, proposed § 117.130(b) would require a hazard identification that must consider hazards that may occur naturally or may be unintentionally introduced; proposed § 117.130(c)(2) would require that the hazard evaluation include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a RTE food is exposed to the environment prior to packaging. The data from recalls and the RFR support a conclusion that *Salmonella* spp. is a hazard in low-moisture RTE food products (such as spices and seasonings, nuts and nut products, and seed products). When RTE foods such as these are exposed to the environment, FDA believes that most facilities producing such foods would identify *Salmonella* spp. as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether *Salmonella* spp. contamination from the environment is reasonably likely to occur in the facility under proposed § 117.130(c)(2). A robust environmental monitoring program for *Salmonella* spp. can verify the effectiveness of sanitation controls designed to prevent *Salmonella* spp. from contaminating food-contact surfaces and food (Ref. 184).

Likewise, the data from recalls and the RFR support a conclusion that *L. monocytogenes* is a hazard in refrigerated or frozen RTE food products (such as dairy products, fresh-cut produce, prepared foods such as sandwiches, and frozen foods). When RTE foods such as these are exposed to the environment, FDA believes that most facilities producing such foods would identify *L. monocytogenes* as a potential hazard under proposed § 117.130(b) and evaluate whether *L. monocytogenes* is reasonably likely to occur in the facility under proposed § 117.130(c)(2). A robust environmental monitoring program for *L. monocytogenes* can verify the effectiveness of sanitation controls designed to prevent *L. monocytogenes* from contaminating food-contact surfaces and food (Ref. 52) (Ref. 144) (Ref. 185) (Ref. 186).

As discussed in section A.5.c of the Appendix to this document, FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes.* However, FDA's current thinking is that there are no currently available indicator organisms for *Salmonella* spp. We request

comment on these findings and conclusions.

Although we are not including an environmental testing provision in this proposed rule, we estimate that an environmental monitoring program for *Salmonella* spp., when implemented appropriately in particular facilities, could impose an incremental annual cost of $3,000–$6,000 per facility. These costs assume that facilities will take 5–15 environmental samples per month, based on facility size, and send the samples to an outside laboratory for testing. This would result in an estimated aggregate cost of $4,000,000 for domestic facilities based on an average of a range of $3,000,000–$5,000,000 (assuming between 50 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $4,400,000 for foreign facilities.

Similarly, we estimate that a requirement for an environmental monitoring program for *Listeria,* when implemented appropriately in particular facilities, could impose an incremental annual cost of $3,000–$6,000 per facility. These costs assume that facilities will take 5–15 environmental samples per month, based on facility size, and send the samples to an outside laboratory for testing. This would result in an estimated aggregate cost of $5,000,000 for domestic facilities based on an average of a range of $4,000,000–$6,000,000 (assuming between 50 and 75 percent of relevant facilities conducting testing) and an estimated aggregate cost of $5,400,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.)

The facilities that could adopt environmental monitoring programs are facilities producing ready-to-eat products exposed to the environment whereby they may become contaminated and for which such testing would be particularly useful as a verification measure for sanitation controls. These estimates exclude facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the ''Consideration of Other Provisions'' section of the PRIA.

FDA requests comment on when and how environmental testing is an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? For example, should we simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur? FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying the environmental pathogen or the indicator organism for which the samples must be tested;
- Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as;
- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.
- Specifying the locations within the facility at which samples must be collected;
- Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
- Be greatest for foods that are likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce the environmental pathogen?
- Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., *L. monocytogenes* which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 144) than for an environmental pathogen that is less frequently introduced?
- Be greater for refrigerated or frozen RTE food products that support growth of *L. monocytogenes* than for those that do not?
- Be greater if there is greater risk of a negative impact on public health (e.g., the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health?
- Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
- Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Ref. 52) (Ref. 185) (Ref. 184) (Ref. 187).
- Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency;
- Requiring data analysis to detect trends.

In addition, with respect to environmental testing for *L. monocytogenes,* FDA requests comment on whether it would be appropriate to distinguish between environmental testing for RTE foods depending on whether the food supports the growth of *L. monocytogenes.* We also request comment on whether there are appropriate indicator organisms for any environmental pathogen other than *L. monocytogenes.* We further request comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

4. Supplier Approval and Verification Program

Section 418(c) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented; and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Section 418(o)(3)(G) of the FD&C Act indicates that the procedures, practices, and processes described in the definition of preventive controls may include supplier verification activities that relate to the safety of food. While FSMA refers only to supplier verification activities, supplier approval, together with supplier verification, is widely accepted in the domestic and international food safety community. The development of a

supplier approval and verification program can be part of a preventive approach. The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. 34). Likewise, Codex addresses the safety of ingredients in the GPFH and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use (Ref. 44).

Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program can help ensure that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place to address the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

The statute does not indicate the specific circumstances where supplier verification would be required or the specific manner in which supplier verification should be performed, and FDA is not including provisions for such verification in this proposed rule. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to determine the specific circumstances and manner where it would be appropriate to perform supplier verification. FDA believes that factors to consider include:

- The nature of the adverse consequences associated with the hazard, such as whether consumption of food containing the hazard may result in serious adverse health consequences or death; and
- The establishment that would be controlling the hazard associated with the raw material or ingredient (e.g., the facility that receives the raw material or ingredient, the supplier of that raw material or ingredient, or even a supplier to the supplier of the raw material or ingredient).

The vast majority of costs related to a supplier approval and verification program are due to verification activities such as audits and testing of raw materials and ingredients, which would likely be selected based on the hazard associated with the raw material or ingredient and where the hazard is controlled. Although we are not including a provision for such a program in this proposed rule, we estimate that a requirement for a supplier approval and verification program, if implemented as part of a preventive approach, could impose an incremental annual cost of $0–$5,000 per supplier facility based on size (number of employees) that undergoes an annual audit. This would result in an estimated aggregate cost of $11,000,000 for domestic facilities and an estimated aggregate cost of $12,000,000 for foreign facilities. (As described in the PRIA, foreign costs are estimated by multiplying the domestic per facility cost by the total number of foreign facilities. See section XIX of this document for a discussion of the PRIA.). We estimate that a requirement for a supplier approval and verification program could impose an incremental annual cost of $7,000–$90,000 per facility based on size (number of employees) for testing of raw materials and ingredients. This would result in an estimated aggregate cost of $5,000,000 for domestic facilities and an estimated aggregate cost of $5,400,000 for foreign facilities. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $250,000 for a very small business) and facilities that are already doing such supplier verification activities. Further details are provided in the ''Consideration of Other Provisions'' section of the PRIA.

FDA requests comment on when and how supplier approval and verification is an appropriate means of implementing the statutory directives set out above. Although we have not included these provisions in the proposed rule, we request comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? Should the requirement be very general, for example, requiring a supplier approval and verification program as appropriate to the facility and the food, when appropriate based on risk? FDA also requests comment on who a supplier approval and verification program should apply to—e.g., should it apply to all facilities that manufacture, process, pack or hold food, or be limited (such as to facilities that manufacture or process food)?

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Requiring that the supplier approval and verification program include a written list of approved suppliers;
- Requiring that, in determining appropriate verification activities, the owner, operator, or agent in charge of a facility consider relevant regulatory information regarding the supplier, including whether the raw material or ingredient is the subject of an FDA warning letter or import alert relating to the safety of the food.
- Specifying circumstances when a supplier approval and verification program would not be required—e.g., when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur; or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.
- Specifying that the type of verification activity be linked to the seriousness of the hazard—e.g., whether to:
- Require an onsite audit when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;
- Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans—e.g., periodic onsite audits, periodic or lot-by-lot sampling and testing of the raw material or ingredient, and periodic review of the supplier's food safety records;
- Specifying requirements for audits—e.g., the qualifications (including training, experience, and conflict of interest) for persons who conduct audits; content of an audit (such as compliance with applicable food safety regulations and, when applicable, compliance with a facility's food safety plan);

• Specifying the frequency of verification activities (e.g., initially, annually, or periodically);

• Specifying whether, for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented;

• Providing for alternative requirements if a supplier is a qualified facility—e.g., documenting that the supplier is a qualified facility and obtaining written assurance that the supplier is producing the raw material or ingredient in compliance with sections 402 and 403(w) of the FD&C Act;

• Specifying those records that would be appropriate for a supplier approval and verification program.

• Providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign food safety authority), for an onsite audit; and

• Specifying that a receiving facility take appropriate action (e.g., discontinuing use of a supplier) if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur.

FDA is aware that many firms that could be affected by supplier verification may be importing their ingredients. We believe that these firms are interested in how a supplier verification component of preventive controls will interface with the regulations FDA is required to issue to implement foreign supplier verification under new section 805 of the FD&C Act. Section 805 requires FDA to issue regulations to require importers to implement foreign supplier verification programs (FSVPs) that are adequate to provide assurances that the importer's foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under sections 418 (concerning hazard analysis and preventive controls) and 419 (concerning produce safety) of the FD&C Act, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.

FDA intends to issue proposed regulations implementing section 805 in the near future. FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent so we do not impose duplicative or unjustified requirements under those two regulations. For example, if a facility imports ingredients, we would not want to subject it to duplicative requirements under a supplier verification provision and an FSVP regulation.

Likewise, FDA is aware that there is great interest from our trading partners on, among other things, the potential overlap between the supplier verification requirements in preventive controls and in FSVP. FDA believes that the approach to harmonization between supplier verification and FSVP described above would adequately address this and comports with our obligations under the World Trade Organization (WTO) trade agreements, including adherence to the principles of the Sanitary and Phytosanitary (SPS) Agreement.

FDA is committed to meeting the requirements of the SPS Agreement and to complying with our obligations under that Agreement as we implement FSMA. In enacting FSMA, Congress explicitly recognized the importance of compliance with international agreements by providing in section 404 of FSMA that ''[n]othing in [FSMA] shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.'' While the statutory provisions in FSMA governing supplier verification by domestic facilities and foreign supplier verification by importers differ in some respects, they are based on common risk-based principles. Implementation of these risk-based principles will assure a general consistency of approach with respect to foreign and domestic facilities regarding, for example, when on-site audits are required. Implementation of FSMA's risk-based principles will also ensure that measures applicable to imports are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection of the United States, taking into account technical and economic feasibility, as required by paragraph 6 of Article 5 of the SPS Agreement.

FDA intends to publish in the very near future a proposed rule to implement FSMA's foreign supplier verification program requirement. FDA will align the comment periods on that proposed rule and the preventive controls rule addressed in this document so that interested parties in the United States and other countries will be able to assess how they will work together in practice. We invite comments to assist FDA in issuing final rules that protect public health and satisfy both FSMA and our international obligations.

K. Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act

1. Overview

This section discusses two measures (review of consumer, customer, and other complaints, and submission of a food safety profile) that FDA is not proposing as specific provisions in proposed part 117, subpart C. Although these measures are not explicitly included in section 418, we believe that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system.

2. Complaints

The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in our HACCP regulations for seafood and juice. Our HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. Our HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as we discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.

Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of submissions to the Reportable Food Registry (Ref. 60) that have suggested that environmental pathogens or food

allergen hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs. (For a discussion of such programs, see section II.A.6.e of this document). Many recall notices identify the results of a state surveillance and testing program as the trigger for a recall (Ref. 188) (Ref. 189) (Ref. 190).

Although this proposed rule does not include a provision regarding a review of complaints, we estimate that a requirement that facility personnel review consumer, customer or other complaints could impose an incremental annual cost of $0– $6,000 per facility based on size (number of employees). This would result in an estimated aggregate annual cost of $11,500,000 for domestic facilities and an estimated aggregate cost of $12,500,000 for foreign facilities.

We request comment on whether and how a facility's review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.

3. Submission of a Facility Profile to FDA

Proposed § 117.126 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records. Currently, information of this type is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. In light of the large number of facilities that would be covered by this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection, if we were to require facilities to do so. Having such plans could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. Facilities would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. We could also more quickly identify facilities that had not established preventive controls for specific hazards of concern to the agency and advise them to fill such gaps to prevent a problem before it occurs. Also, FDA could use the plans in evaluating the need for guidance on specific hazards or controls and prioritizing guidance to areas where it is needed most.

FDA believes that there are significant obstacles to realizing these benefits from submission of food safety plans, however. The agency would expect to receive a very large number of plans. Further, these plans would be expected to vary significantly in content and format. Assimilating the underlying information in a way that would be useful to the agency would be an immense challenge. Moreover, not all of the information in such plans may be essential to realizing the potential benefits described above. Therefore, to most efficiently realize the potential benefits of having certain information prior to an inspection, we request comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan. This information, which could be referred to as a ''facility profile,'' could be submitted through an electronic form using a menu selection approach. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack, foods that are at increased risk for a food safety problem; to facilities that appear to have insufficient controls to prevent a problem; or to facilities using a control we conclude is ineffective at controlling hazards. The data elements for a facility profile could include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;
- Preventive controls established for each of the identified hazards;
- Third-party audit information (have you had one and which audit firm(s));
- Preventive control employee training conducted;
- Facility size (square footage);
- Full time operation or seasonal;
- Operations schedule;

This information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. We also request comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

We have previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (**Federal Register** of May 11, 2012, 77 FR 27779). In that notice, we noted that FSMA added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. We also noted that food facility profile information voluntarily provided to FDA will help us to determine whether a firm is high-risk or non-high-risk and that we will use the profile information to assist us in determining the frequency at which we will inspect the firm. In contrast to the voluntary submission of food facility profile information described in that notice, in this document we are requesting comment on whether the submission of such information should be required.

XIII. Proposed New Provisions for Modified Requirements (Proposed Part 117, Subpart D)

FSMA provides for the establishment of modified requirements for certain facilities under certain circumstances. In this section of this document, we propose such modified requirements.

A. Proposed § 117.201—Modified Requirements That Apply to a Qualified Facility

1. Requirements of Section 418(l) of the FD&C Act

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' As discussed in section II.B.1.b of this document, section 418(l)(1) of the FD&C Act establishes the conditions for a facility to be a ''qualified facility'' based on either business size (section 418(l)(1)(B) of the FD&C Act) or a combination of the average monetary value of the food sold and the value of food sold to qualified end users as compared to all other purchasers (section 418(l)(1)(C) of the FD&C Act), and proposed § 117.3 would establish a definition for ''qualified facility'' based on section 418(l)(1).

Sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility is exempt from the requirements of sections 418(a) through (i) and (n) of the FD&C Act (i.e., the requirements for hazard analysis and risk-based preventive controls), but must instead submit two types of documentation to the Secretary of HHS. The first type of required documentation relates to food safety practices at the facility, and section 418(l)(2)(B)(i) provides two options for satisfying this documentation requirement. Under section 418(l)(2)(B)(i)(I), the qualified facility may choose to submit documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under section 418(l)(2)(B)(i)(II), the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary of HHS, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law.

The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility. Under section 418(l)(2)(B)(ii) of the FD&C Act, the facility must submit documentation, as specified by the Secretary of HHS in a guidance document, that the facility is a qualified facility under section 418(l)(1)(B) of the FD&C Act or section 418(l)(1)(C) of the FD&C Act.

Section 418(l)(7)(A) of the FD&C Act requires that a qualified facility that is exempt from the requirements under sections 418 (a) through (i) and subsection (n), and that does not prepare documentation under section 418(l)(2)(B)(i)(I), provide notification to consumers by one of two procedures, depending on whether a food packaging label is required on the food. With respect to a food for which a food packaging label is required by the Secretary of HHS under any other provision of the FD&C Act, section 418(l)(7)(A)(i) of the FD&C Act requires that a qualified facility include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed. With respect to a food for which a food packaging label is not required by the Secretary of HHS under any other provisions of the FD&C Act, section 418(l)(7)(A)(ii) of the FD&C Act requires that a qualified facility prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

2. Proposed § 117.201(a)—Documentation to be Submitted

a. Proposed § 117.201(a)(1)—Documentation that the facility is a qualified facility. Proposed § 117.201(a)(1) would require that a qualified facility submit to FDA documentation that the facility is a qualified facility. Consistent with the conditions in section 418(l)(1) of the FD&C Act for a facility to be a qualified facility, and our proposed definition (proposed § 117.3) of ''qualified facility,'' the documentation would be directed to either the status of the facility as a very small business (as would be defined in proposed § 117.3) or the applicability of conditions for average annual monetary value and the value of food sold to qualified end users as compared to other purchasers (as would be included in the definition of qualified facility in proposed § 117.3). As discussed further in section XIII.A.5, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 117.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(1). We would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to the proportion of sales to qualified end users.

Proposed § 117.201(a)(1) also would establish that, for the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 418(l)(1)(C) of the FD&C Act, and the definition of very small business in proposed § 117.3, allow adjustment for inflation. To establish a level playing field for all facilities that may satisfy definition of a qualified facility, we are proposing to establish the baseline year for the calculation in proposed § 117.201(a)(1). We are proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. We tentatively conclude that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II)—i.e., $500,000—and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted.

b. Proposed § 117.201(a)(2)—Documentation related to food safety practices at a facility. Proposed § 117.201(a)(2) would provide two options for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility. Proposed § 117.201(a)(2)(i) would allow qualified facilities to submit documentation to demonstrate that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy this requirement.

Proposed § 117.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(I) of the FD&C Act, except that proposed § 117.201(a)(2)(i) would specify monitoring the *performance of the* preventive controls to ensure that such controls are effective (emphasis added). As discussed in section II.B.1.a of this document, under the overall framework of the proposed requirements that would be established in subpart C, monitoring is directed to performance of preventive controls. Thus, proposed § 117.201(a)(2)(i) is consistent with the statute and the overall framework of this proposed rule.

Proposed § 117.201(a)(2)(ii) would provide another option for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility by allowing qualified facilities to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Proposed § 117.201(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(II) of the FD&C Act.

As discussed further in section XIII.A.5 of this document, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility (1) has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or (2) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(2). We would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications.

3. Proposed § 117.201(b)—Procedure for Submission

Proposed § 117.201(b) would require that qualified facilities submit the documentation that would be required by proposed § 117.201(a) by one of two procedures. Proposed § 117.201(b)(1) would provide an option to submit documentation electronically at *http://www.access.fda.gov* by following the instructions to be provided on that Web page. Proposed § 117.201(b)(1) would inform facilities that this Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Although electronic submission is not required, proposed § 117.201(b)(1) would encourage electronic submission, which is efficient for FDA and should also be efficient for facilities. Electronic submission generally would be available 24 hours a day, 7 days a week, unless the Web site is experiencing technical difficulties or is undergoing maintenance.

Proposed § 117.201(b)(1) would provide an option to submit documentation by mail. A qualified facility would have the option to submit documents in a paper format or in an electronic format on a CD–ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. ''Mail'' would include the U.S. mail and businesses that can deliver documents to the address provided. We would recommend that an owner, operator or agent in charge of a qualified facility submit by mail only if the qualified facility does not have reasonable access to the Internet. It is not efficient for FDA to receive such documents by mail.

We are not proposing to provide for submission by fax. We expect that there may be technical difficulties or loss or mix-up of some submitted information if we were to allow for submission by fax.

In section XIII.A.5 of this document, we discuss the information that would be submitted.

4. Proposed § 117.201(c)—Frequency of Submission

Proposed § 117.201(c)(1) would require that the documentation that would be required by section § 117.201(a) be submitted to FDA initially within 90 days of the applicable compliance date of the rule. As discussed in section VII of this document, the compliance date for a small business would be 2 years after the date of publication of the final rule and the compliance date for a very small business would be 3 years after the date of publication of the final rule.

Proposed § 117.201(c)(2) would require that the documentation that would be required by proposed § 117.201(a) also must be resubmitted to FDA at least every 2 years, or whenever there is a material change to the information that would be described in proposed § 117.201(a). For the purposes of proposed § 117.201, a material change would be one that changes whether or not a facility is a ''qualified facility.'' The status of a facility as a qualified facility has the potential to change materially on an annual basis. For example, if a facility reports that it is a very small business (e.g., under one option identified in proposed § 117.3, has less than $250,000 in total annual sales of food, adjusted for inflation), its total annual sales of food likely would change on an annual basis, and could change so as to exceed $250,000. Likewise, if a facility reports that it otherwise satisfies the definition of a qualified facility, its total annual sales of food and value of food sold to qualified end users as compared to other purchasers likely would change on an annual basis, and could change so as to no longer satisfy the definition of a qualified facility.

5. Information That Would Be Submitted

Consistent with section 418(l)(2)(B)(ii) of the FD&C Act, we intend to issue guidance regarding documentation that would be submitted under proposed § 117.201(a)(1) to demonstrate that a facility is a qualified facility. As discussed in sections XIII.A.2.a and XIII.A.2.b of this document, we tentatively conclude that certified statements from the owner, operator, or agent in charge of a qualified facility would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 117.201(a)(1) and (2).

To inform the guidance required under section 418(l)(2)(B)(ii) of the FD&C Act and any other guidance that may be useful in addressing questions regarding submission of documentation under this subpart, in this document we request comment on an option we are considering regarding the submission of documentation. Specifically, we request comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 117.201(a).

A facility that identifies itself as a qualified facility would be prompted to provide the following information by checking items that apply. Such items could include:

- Whether the facility satisfies the conditions for a qualified facility:
  - As a very small business as that term would be defined in proposed § 117.3;
  - As a facility that otherwise satisfies the definition of qualified facility in proposed § 117.3 based on average monetary value of sales and value of food sold to qualified end users as compared to other purchasers; or
  - Both of the above.
- Whether the facility:
  - Has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective;
  - Is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries; or
  - Both of the above.

In essence, such a system would provide for self-certification that the

facility has appropriate information demonstrating that the facility is a qualified facility and either has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Such a system may include a statement reminding submitters that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. Using such a system, a qualified facility could update the documentation required by proposed § 117.201(a) during the biennial registration required by section 415(a)(3) of the FD&C Act.

6. Proposed § 117.201(d)—Notification to Consumers

Proposed § 117.201(d) would require that a qualified facility that does not submit the type of documentation directed to food safety practices described in § 117.201(a)(2)(i) provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities) consistent with section 418(l)(7) of the FD&C Act. If a food packaging label is required, proposed § 117.201(d)(1) would require that the required notification appear prominently and conspicuously on the label of the food. If a food packaging label is not required, proposed § 117.201(d)(2) would require that the required notification appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

Proposed § 117.201(d) would enable consumers to contact the facility where a food was manufactured or processed (e.g., if the consumer identifies or suspects a food safety problem with a product) irrespective of whether the food product bears a label. The use of the term ''business address'' in section 418(l)(7) of the FD&C Act contrasts with Congress' use of a different term, ''place of business,'' in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. Our regulations interpret ''place of business'' as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 CFR 101.5(d)). We tentatively conclude that the use of the term ''business address'' in section 418(l)(7) demonstrates Congress' intent to require the facility's full address, including the street address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices under section 418(l)(2)(B)(i)(I) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the ''place of business'' labeling regulation (§ 101.5(d)) to be adequate for notification to consumers for foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 418(l)(7) for the facility's ''business address'' to appear on the food label. Requiring the complete business address for this purpose is consistent with our guidance to industry on the labeling of dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Ref. 130). When proposed § 117.201(d) would apply to a food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the ''place of business'' required under section 403(e)(1) of the FD&C Act and 21 C.F.R. 101.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. We seek comment on this interpretation.

7. Records

Proposed § 117.201(e)(1) would require that a qualified facility maintain records relied upon to support the documentation that would be required by § 117.201(a). Proposed § 117.201(a) would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the documentation that would required by proposed § 117.201(a). Proposed § 117.201(e)(2) would establish that the records that a qualified facility must maintain are subject to the requirements of subpart F of part 117. As discussed in section XV of this document, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 117, including provisions for retention of records and for making records available for official review. Together, proposed § 117.201(a) and (b) would make the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request. We tentatively conclude that it is appropriate to require that the records relied upon to support a self-certified statement be retained and made available to FDA upon request.

B. Proposed § 117.206—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Briefly, as relevant to proposed § 117.206, specific provisions of section 418 of the FD&C Act require, in relevant part, that the owner, operator, or agent in charge of a facility:

- Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and develop a written analysis of the hazards (section 418(b) of the FD&C Act);
- Identify and implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c) of the FD&C Act);
- Monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act to provide assurances that the outcomes described in section 418(c) shall be achieved (section 418(d) of the FD&C Act);
- Establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective * * * appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; all affected food is evaluated for safety; and all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e) of the FD&C Act);

• Verify that the preventive controls are adequate to control the hazards the owner, operator, or agent is conducting monitoring and is making appropriate decisions about corrective actions and the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards and there is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f) of the FD&C Act);

• Maintain, for not less than 2 years, records documenting the monitoring of the preventive controls instances of nonconformance material to food safety and instances when corrective actions were implemented (section 418(g) of the FD&C Act);

• Prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards and identifying the preventive controls adopted to address those hazards (section 418(h) of the FD&C Act);

• Conduct a reanalysis under section 418 (b) of the FD&C Act whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier (section 418(i) of the FD&C Act).

In addition to these requirements directed to the owner, operator, or agent in charge of a facility, section 418(m) of the FD&C Act provides, in relevant part, that the Secretary may, by regulation, exempt or modify the requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment.

2. Approach to Modified Requirements Under Section 418(m) of the FD&C Act

As discussed in section X.D.4 of this document, proposed § 117.7 would both provide that subpart C does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.7(a)) and establish that such a facility is subject to modified requirements in proposed § 117.206 (proposed § 117.7(a)). In the remainder of our discussion of these modified requirements, we refer to ''packaged food that is not exposed to the environment'' as ''unexposed packaged food,'' and we refer to ''unexposed refrigerated packaged food that requires time/temperature control for safety'' as ''unexposed refrigerated packaged TCS food.'' As noted in section X.D.2 of this document, we consider ''not exposed to the environment'' and ''unexposed'' to mean that the food is in a form that prevents any direct human contact with the food. The modified requirements in proposed § 117.206 would apply to unexposed refrigerated packaged TCS food. In essence, proposed § 117.7 distinguishes between unexposed packaged food and unexposed refrigerated packaged TCS food. This distinction is based on hazards that are reasonably likely to occur during the storage of unexposed refrigerated packaged TCS food, but are not reasonably likely to occur during the storage of unexposed packaged food that does not require time/temperature control for safety.

When an unexposed packaged food is a refrigerated TCS food, the principal hazard for the unexposed refrigerated packaged TCS food is the potential for the growth of, or toxin production by, microorganisms of public health significance. Information about this hazard for TCS foods in general (i.e., not limited to unexposed packaged food) is widely available (Ref. 137) (Ref. 138) (Ref. 139) (Ref. 140). In brief, the need for time/temperature control is primarily determined by (1) the potential for contamination with microorganisms of public health significance and (2) the potential for subsequent growth and/or toxin production. Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods (62 FR 8248, February 24, 1997).

Failure to maintain foods at appropriate temperatures may result in the growth of microorganisms that may have contaminated the foods before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness (62 FR 8248). A review of the factors that influence microbial growth and an analysis of microbial hazards related to time/temperature control of foods for safety can be found in a report (issued by the Institute of Food Technologists (IFT) under contract to FDA) on the Evaluation and Definition of Potentially Hazardous Foods (Ref. 140) (the IFT report). The IFT report describes properties of common food commodities and the microbiological hazards that may occur from consuming particular food commodities, emphasizing microbial concerns that would be associated with temperature abuse of the products. The IFT report discusses foods for which time/temperature control may be necessary for safety (Ref. 140). Most foods that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including *Clostridium botulinum, Bacillus cereus* and *C. perfringens.* If refrigerated foods are exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of *C. botulinum* and *B. cereus* can grow at refrigeration temperatures, e.g., some strains of *B. cereus* grow at 39 °F (4 °C) and some strains of *C. botulinum* grow at 38 °F (3.3 °C) (Ref. 173).

Examples of refrigerated foods that are capable of supporting the growth of pathogenic sporeformers such as *B. cereus, C. botulinum* and *C. perfringens* include many prepared soups, filled pastas, and sauces. In addition, some foods may be contaminated with *L. monocytogenes,* which, as described in section II.D.2.a, can also grow at refrigeration temperatures. Examples of foods that support the growth of *L. monocytogenes* include milk and soft cheese. Producers of refrigerated foods minimize the contamination of foods with pathogens to the extent possible, particularly if the pathogen can grow under refrigeration conditions. Growth of pathogens is very slow under refrigeration, and the lower the temperature the longer the time for growth (Ref. 140). Conversely, as refrigeration temperature increases, the growth rate of strains of pathogens that grow slowly under refrigeration increases and food temperatures may get high enough that pathogens that cannot grow at normal refrigeration temperatures (generally in the range of 41–45 °F (5 °C–7 °C)) begin to grow (Ref. 140). For example, the strains of *C. botulinum* that have caused most of the outbreaks in the United States do not grow and produce toxin until the temperature reaches 50 °F (10 °C) (Ref. 3). Additional information about the time/temperature control of food to address the potential for microorganisms of public health significance to grow or produce toxins is available in books on food microbiology that are available for purchase.

Such information is sufficiently well-known and accepted that we tentatively conclude that the outcome of each individual hazard analysis for an unexposed refrigerated packaged TCS food, conducted by the owner, operator, or agent in charge of each individual facility solely engaged in the storage of unexposed packaged food, would be the same. That outcome would be that the potential for the growth of, or toxin production by, microorganisms of public health significance is a hazard reasonably likely to occur in any unexposed refrigerated packaged TCS food. Likewise, information about appropriate preventive controls for this hazard is widely available (Ref. 191) (Ref. 139). Such information is sufficiently well-known and accepted that we tentatively conclude that the appropriate preventive control selected by each individual facility solely engaged in the storage of unexposed packaged food would be adequate controls on the temperature of any unexposed refrigerated packaged TCS food.

In light of the general recognition of the hazard that is reasonably likely to occur in a refrigerated packaged TCS food and the appropriate preventive control for that hazard, we tentatively conclude that it is appropriate to specify the hazard and appropriate preventive control in the regulation. Under this approach, it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct its own hazard analysis and reach its own conclusion about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Instead, what would remain for the facility to do to comply with section 418 of the FD&C Act for the activity of storing an unexposed refrigerated packaged TCS food would be a subset of the requirements for hazard analysis and risk-based preventive controls that would be established in proposed subpart C to implement section 418 of the FD&C Act. None of these requirements would require a qualified individual. This subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);
- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act). We seek comment on the proposed list of modified requirements.

We also tentatively conclude that it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged food to conduct the reanalysis specified in section 418(i) of the FD&C Act with respect to storing an unexposed refrigerated packaged TCS food. As discussed in section XII.G.6 of this document, reanalysis would apply in determining whether to apply any additional preventive controls and in determining whether to update the written plan. Under our approach, it is FDA who has identified the preventive control, and it would be FDA's responsibility, through rulemaking, to require any additional preventive control. Likewise, under our approach, the facility would not be required to develop a food safety plan and, therefore, would not need to update the plan. If, for example, the facility changes its procedures for temperature control, the specific activities that the facility would be required to conduct (monitoring temperature; taking appropriate corrective actions if there is a problem with temperature control; conducting applicable verification activities; and establishing and maintaining appropriate records) would be adequate to address the change in procedure for temperature control.

3. Proposed § 117.206—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Food that Is Not Exposed to the Environment

Proposed § 117.206(a) would require that the owner, operator or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment conduct certain activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance. Briefly, those activities would encompass:

- Establishing and implementing temperature controls (proposed § 117.206(a)(1));
- Monitoring the temperature controls (proposed § 117.206(a)(2));
- If there is a problem with the temperature controls for such refrigerated packaged food, taking appropriate corrective actions (proposed § 117.206(a)(3));
- Verifying that temperature controls are consistently implemented (proposed § 117.206(a)(4)); and
- Establishing and maintaining certain records (proposed § 117.206(a)(5)).

More specifically, proposed § 117.206(a)(1) would require that the owner, operator, or agent in charge of a facility subject to proposed § 117.206 establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food. There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 117.206 would need to know the answers to in order to comply with proposed § 117.206 for any given unexposed refrigerated packaged food:

- Is the food a TCS food?
- If the food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 117.206 can obtain the answers to these questions are: (1) through information provided by the manufacturer, processor, or packer of the food, either in documents exchanged between the parties in the course of business or by label statements placed on the food by the manufacturer, processor, or packer of the food; and (2) through applicable scientific and technical support literature.

As discussed in section X.D.2 of this document, a citizen petition submitted to FDA (Docket No. FDA–2011–P–0561) asserted that facilities work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts. If the conditions for storage are not formalized in written contracts or by other means (e.g., through documents of the trade that travel with a food product when it moves within the supply chain), information relevant to safe storage of the food may be provided by the manufacturer, processor, or packer of the food on the food label. For example, in 1997 FDA published guidelines for labeling food that needs refrigeration by consumers due to the potential for the food to be rendered unsafe due to the growth of infectious or toxigenic microorganisms if ''temperature abused'' (62 FR 8248,

February 24, 1997). FDA recommended that foods requiring refrigeration by the consumer for safety be labeled ''IMPORTANT Must be Kept Refrigerated to Maintain Safety'' (62 FR 8248 at 8251) and that foods that are intended to be refrigerated but that do not pose a safety hazard if temperature abused be labeled more simply—e.g.; ''Keep refrigerated.'' Such labeling can provide facilities with the information to identify TCS foods. We tentatively conclude that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food. We request comment on this tentative conclusion.

In a situation where the owner, operator or agent in charge of a facility does not have information from the manufacturer, processor, or packer of the food about whether an unexposed refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food, the owner, operator, or agent in charge of the facility could either consult the scientific and technical literature to determine whether a particular food is a TCS food or assume that any unexposed refrigerated packaged food is a TCS food. Information about foods that are TCS foods, and about the appropriate temperatures to address the potential for microorganisms of public health significance to grow, or produce toxin, in food are well-established in the scientific literature. Documents prepared by or on behalf of FDA regarding appropriate time/temperature controls for safety (Ref. 173) (Ref. 140) provide numerous references to the primary scientific literature and serve as the basis for time/temperature controls for a variety of foods. The two temperatures commonly cited in these documents as maximum temperatures for safe storage of refrigerated food are 41 °F (5 °C) and 45 °F (7 °C). The cited maximum temperature depends on the food; in some cases, a maximum storage temperature is established through rulemaking in a regulation. For example:

- Our regulations for the prevention of *Salmonella* Enteritidis in shell eggs during production, storage, and transportation (§ 118.4(e)) and for refrigeration of shell eggs held for retail distribution (§ 115.50(b)(2)) require that eggs be held and transported at a temperature not to exceed 45°F (7°C).
- The PMO provides for pasteurized Grade ''A'' milk and milk products to be held at 45°F (7°C) (Ref. 37).
- The FDA Food Code, which has been widely adopted in state laws, recommends holding most potentially hazardous (TCS) food at 41°F (7°C) or lower (Ref. 191).

Storage of refrigerated food at or below one of these two temperatures (i.e., 41 °F (5 °C) or 45 °F (7 °C)) consistent with storage temperatures required by regulation or recommended in widely adopted documents such as the PMO and the FDA Food Code would satisfy proposed § 117.206(a).

We consider frozen food to be a subset of refrigerated food. The temperature and time required for a frozen food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen food being subject to temperatures that allow some thawing in storage and distribution, we are not aware of situations in which frozen foods have been associated with the food becoming unsafe. Thus, we tentatively conclude that it would be rare for an unexposed frozen packaged food to be a TCS food.

Proposed § 117.206(a)(2) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food monitor the temperature controls established for unexposed refrigerated packaged TCS food with sufficient frequency to provide assurance that they are consistently performed. Monitoring can be done by use of a continuous temperature-recording device (e.g., a recording thermometer) that indicates and records the temperature accurately within the refrigeration compartment with a visual check of the recorded data at least once per day. Monitoring as would be required by proposed § 117.206(a)(2) would provide the owner, operator, or agent in charge of the facility with factual information with which to judge whether the temperature control is operating as intended. Proposed § 117.206(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 117.140(a) in subpart C in that proposed § 117.206(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 117.206(a)(5)(i)) would demonstrate the frequency of monitoring. We request comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

Proposed § 117.206(a)(3) would require that, if there is a problem with the temperature controls for unexposed refrigerated packaged TCS food, the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food take appropriate corrective actions to correct a problem with the control of temperature for any refrigerated packaged food and reduce the likelihood that the problem will recur (proposed § 117.206(a)(3)(i)); evaluate all affected food for safety (proposed § 117.206(a)(3)(ii)); and prevent the food from entering commerce, if the owner, operator, or agent in charge of a facility cannot ensure the affected food is not adulterated under section 402 of the FD&C Act (proposed § 117.206(a)(3)(iii)). Such corrective actions would be necessary if, for example, there was a failure to maintain adequate temperature control. Proposed § 117.206(a)(3) is modified relative to the analogous proposed requirement for corrective actions that would be established in proposed § 117.145(a) in subpart C in that proposed § 117.206(a)(3) would not require written procedures for corrective actions. In essence, there is a single action to correct the problem (i.e., to restore temperature control), followed by the need to evaluate the food for safety and to prevent food from entering commerce when appropriate. The corrective actions taken, including information to document that product was not exposed to temperatures and times that would compromise the safety of the product, would be documented in records subject to agency review. It may be necessary for the owner, operator, or agent in charge of the facility to consult with the applicable manufacturer, processor, or packer of the food to determine the appropriate disposition of the food.

Proposed § 117.206(a)(4)(i) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged food verify that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices. As discussed in section XII.G.5.a of this document, calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance temperatures are adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed

refrigerated packaged TCS food. Proposed § 117.206(a)(4)(i) is analogous to proposed § 117.150(d)(2) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.

Proposed § 117.206(a)(4)(ii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing records of calibration within a reasonable time after the records are made. As discussed in section XII.G.5.b of this document, the purpose of the review of records would be to ensure that the records are complete and that the preventive controls are effective. If temperature monitoring and recording devices are not properly calibrated, the temperature controls may not be effective. As discussed in section XII.G.5.b of this document, the review of calibration records will depend in part on the frequency with which calibrations occur.

Proposed § 117.206(a)(4)(iii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food verify that temperature controls are consistently implemented by reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made. As discussed in section XII.G.5.b of this document, the purpose of the review of records would be to ensure that the records are complete, that the temperatures recorded were adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance in an unexposed refrigerated packaged TCS food, and that appropriate actions were taken to correct any problem with the control of temperature for any unexposed refrigerated packaged TCS food. A weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records. Proposed § 117.206(a)(4)(iii) is analogous to proposed § 117.150(d)(2)(ii) in subpart C, which would establish a verification requirement for review of records of monitoring and corrective action records within a week after the records are made.

Proposed § 117.206(a)(4) is modified relative to the analogous proposed verification requirements in proposed § 117.150 in that proposed § 117.206(a)(4) would not require validation or reanalysis. There is a single control to verify, which limits the need for many of the verification procedures that might otherwise apply. As noted above, the temperatures to control growth of microbial pathogens are well documented and do not require validation that they are effective in controlling the potential for microorganisms of public health significance to grow, or produce toxin, in food. The reasons for not requiring reanalysis were discussed in section XIII.B.2. Proposed § 117.206(a)(4) also is modified relative to the analogous proposed verification requirements in proposed § 117.150 in that proposed § 117.206(a)(4) would not require that a qualified individual perform or oversee the review of records of calibration or records of monitoring and actions taken to correct a problem with the control of temperature. The nature of these records does not require the qualifications that would be required under proposed § 117.155(b).

Proposed § 117.206(a)(5) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged food establish and maintain records documenting the monitoring of temperature controls for any unexposed refrigerated packaged TCS food (proposed § 117.206(a)(5)(i)); records of corrective actions taken when there is a problem with the control of temperature for any unexposed refrigerated packaged TCS food (proposed § 117.206(a)(5)(ii)); and records documenting verification activities (proposed § 117.206(a)(5)(iii)). The records that document monitoring would be used to verify that the temperature controls are effectively and significantly minimizing or preventing the growth of, or toxin production by, microorganisms of public health significance. The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken. The records that document verification activities would be used to document that this key element of a food safety plan has been implemented. These records would be necessary to demonstrate compliance with the requirements and as such would be useful to inspectors and auditors. Proposed § 117.206(a)(5) is analogous to provisions in proposed §§ 117.140(c), 117.145(d), and 117.150(f) in subpart C, which would require documentation of monitoring, corrective actions, and verification activities, respectively.

Proposed § 117.206(b) would establish that the records that a facility must establish and maintain under proposed § 117.206(a)(5) are subject to the requirements of proposed subpart F. Proposed subpart F would establish requirements that would apply to all records that would be required under proposed part 117. We describe the requirements of proposed subpart F in section XV of this document. Proposed § 117.206(b) is analogous to proposed § 117.175(b) in subpart C.

XIV. Proposed New Provisions for Withdrawal of an Exemption Applicable to a Qualified Facility (Proposed Part 117, Subpart E)

A. Requirements of Section 418 of the FD&C Act

Section 418(l)(3)(A) of the FD&C Act specifies that, in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under section 418(l) of the FD&C Act, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under section 418(l) of the FD&C Act. Section 418 does not expressly prescribe the procedures for withdrawing an exemption provided to a qualified facility under section 418(l). We tentatively conclude that it is appropriate to be transparent about the process we would use to withdraw an exemption and that we should include the process in the proposed rule.

B. Proposed § 117.251—Circumstances That May Lead FDA To Withdraw an Exemption Applicable to a Qualified Facility

1. Proposed § 117.251(a)—Withdrawal of an Exemption in the Event of an Active Investigation of a Foodborne Illness Outbreak

Proposed § 117.251(a) would provide that FDA may withdraw the exemption that would be applicable to a qualified facility under proposed § 117.5(a) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility. Proposed § 117.251(a) would implement the statutory language of section 418(l)(3)(A) of the FD&C Act. As discussed in section II.A.6.c of this document, an outbreak of foodborne illness is the occurrence of two or more

cases of a similar illness resulting from the ingestion of a common food. Food can become contaminated at many different steps in the farm-to-table continuum: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; in restaurants; and in the home. When foodborne illness is associated with food, a traceback investigation may enable us to directly link the illness to the facility or facilities that manufactured, processed, packed, and/or held the food.

For example, in February 2007, CDC notified FDA of a multi-state outbreak of *Salmonella* Tennessee infections associated with the consumption of peanut butter (73 FR 55115 at 55118, September 24, 2008). Peanut butter is a non-perishable packaged food, sold in jars. Consumers who became ill had open jars of peanut butter available for testing. Investigators were able to test samples of peanut butter taken from the jars and confirm the presence of *Salmonella* Tennessee in the peanut butter. Investigators were able to identify the manufacturer through information required to be on the label of the jars (21 CFR 101.5(a)) and through a product code the manufacturer had voluntarily placed on the jars. This information made it possible for FDA to visit the manufacturing facility the day after we learned of the outbreak from CDC. Investigators were able to use the product code to look in the manufacturing facility for unopened jars of peanut butter manufactured at the same time as the jars available from consumers. Investigators took samples of peanut butter from these unopened jars and confirmed the presence of *Salmonella* Tennessee in those samples. Because investigators uncovered conditions at the manufacturer's facility that were likely to have caused the contamination and obtained a positive environmental sample, investigators saw no need to further trace the peanuts back to the farm where the peanuts were grown (73 FR 55115 at 55118). In circumstances such as the 2007 peanut butter outbreak, the available data and information from the investigation directly linked the outbreak of foodborne illness to the manufacturing facility.

2. Proposed § 117.251(b)—Withdrawal of an Exemption Based on Conduct or Conditions Associated With a Qualified Facility

Proposed § 117.251(b) would provide that FDA may withdraw the exemption applicable to a qualified facility under proposed § 117.5(a) if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. As an example, we may receive reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a qualified facility that manufactured, processed, packed or held the food. If our investigation finds conduct or conditions associated with the facility that are material to the safety of the food (for example, conduct or conditions that likely led to the contamination of the food), we would consider withdrawing the exemption applicable to the facility under proposed § 117.5(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a qualified facility, we discover conditions and practices that are likely to lead to contamination of food with microorganisms of public health significance, we would consider withdrawing the exemption provided to the facility under proposed § 117.5(a) if doing so would be necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

C. Proposed § 117.254—Issuance of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.254(a) would provide that, if FDA determines that an exemption applicable to a qualified facility under proposed § 117.5(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. We intend to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record.

Proposed § 117.254(b) would require that an FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Director and Director of the Center for Food Safety and Applied Nutrition are examples of an FDA official senior to the Director of the Office of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K (Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition is consistent with current FDA practices when dealing with foreign firms.

Proposed § 117.254(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the qualified facility. The requirements of section 418 of the FD&C Act are directed to the owner, operator, or agent in charge of a facility. We tentatively conclude that the statutory language of section 418 enables FDA to issue an exemption withdrawal order to any of these persons.

Proposed § 117.254(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

D. Proposed 117.257—Contents of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.257(a) through (i) would require that an order to withdraw an exemption applicable to a qualified facility under § 117.5(a) include the following information:

- (a) The date of the order (proposed § 117.257(a));
- (b) The name, address and location of the qualified facility (proposed § 117.257(b));
- (c) A brief, general statement of the reasons for the order, including information relevant to:
- (1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
- (2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility (proposed § 117.257(c)).
- (d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order (proposed § 117.257(d));
- (e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E (proposed § 117.257(e));
- (f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing

under part 16 of this chapter (21 CFR part 16), with certain exceptions described in proposed § 117.270 (proposed § 117.257(f));

• (g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); (proposed § 117.257(g)); and

• (h) The name and the title of the FDA representative who approved the order (proposed § 117.257(i)).

FDA tentatively concludes that the requirements that we propose in § 117.257 would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal with adequate notice of the basis for our determination to withdraw the exemption and of their opportunity to appeal our determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393 orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16.

E. Proposed § 117.260—Compliance With, or Appeal of, an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.260(a) would require that the owner, operator, or agent in charge of a qualified facility that receives an order under § 117.251 to withdraw an exemption applicable to that facility under § 117.5(a) either comply with applicable requirements of this part within 60 calendar days of the date of the order; or appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 117.264. We tentatively conclude that either of the two circumstances that could result in our determination that an exemption should be withdrawn (as described in proposed § 117.251) warrant prompt compliance with the rule in the interest of public health. We tentatively conclude that ten calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.260(b) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing under proposed § 117.260(b) would not prevent FDA from simultaneously detaining food from the facility under section 304(h) of the FD&C Act, seizing food from the facility under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act.

Proposed § 117.260(c) would require that, if the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order. Proposed § 117.260(c) would make clear that the 60 calendar day time frame for compliance applies regardless of whether the owner, operator, or agent in charge of a facility requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of public health.

F. Proposed § 117.264—Procedure for Submitting an Appeal

Proposed § 117.264(a) would require that, to appeal an order to withdraw an exemption applicable to a qualified facility under § 117.5(a), the owner, operator, or agent in charge of the facility must (1) submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order; and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

Allowing the owner, operator, or agent in charge of the facility to submit an appeal in person, by mail, email, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. Email and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the ten day time frame for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 117.264(a) would repeat the 10 calendar day time frame that would be established in proposed § 117.260(a)(2) and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. We are proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that we would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 117.264(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 117.5(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 117.267. Requesting an informal hearing does not mean that a hearing will be held, because we may deny the request (see discussion of proposed § 117.267(b) in the next section of this document). However, if the owner, operator, or agent in charge of the facility does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the facility will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

G. Proposed § 117.267—Procedure for Requesting an Informal Hearing

Proposed § 117.267(a)(1) would provide that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility may request an informal hearing. Proposed § 117.267(a)(1) would restate an option that would be included in proposed § 117.264(b) to highlight the opportunity to request an informal hearing. Proposed § 117.267(a)(2) would require that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the

facility must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of the order. We tentatively conclude that requiring submission of a request for an informal hearing in writing at the time that the owner, operator, or agent in charge of the facility would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.267(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 117.267(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial. Under proposed § 117.264(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

H. Proposed § 117.270—Requirements Applicable to an Informal Hearing

Proposed § 117.270(a) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA. We tentatively conclude that, if we grant a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative time frame as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed 117.270(b) would establish that the presiding officer may require that a hearing conducted under this subpart E be completed within 1 calendar day, if appropriate. We tentatively conclude that, if we grant a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.270(c)(1) through (7) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

- (1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
- (2) A request for a hearing under this subpart E must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.
- (3) Section 117.274, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.
- (4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.
- (5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.
- (6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.
- (7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 117.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 418 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that an exemption provided to a qualified facility under proposed § 117.5(a) should be withdrawn. However, we tentatively conclude as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a qualified facility subject to withdrawal of the facility's exemption. We also tentatively conclude that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may

petition for a stay of the decision or action under § 10.35. Proposed § 117.270(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing an exemption provided under proposed § 117.5(a). The circumstances that may lead FDA to withdraw an exemption include an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility, or our determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. Such circumstances require prompt action. Under § 16.120, a qualified facility that disagrees with FDA's decision to withdraw an exemption provided under § 117.5(a) has an opportunity for judicial review in accordance with § 10.45.

I. Proposed § 117.274—Presiding Officer for an Appeal and for an Informal Hearing

Proposed § 117.274 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of an exemption applicable to a qualified facility must be approved by a District Director or an official senior to a District Director. It is therefore necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the facility is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the facility is located, for example in the event the Regional Food and Drug Director for the region in which the facility is located is the FDA official who approved the withdrawal order. Any Office Director of FDA's Office of Regulatory Affairs could preside at a hearing, provided that the Office Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice.

J. Proposed § 117.277—Time Frame for Issuing a Decision on an Appeal

Proposed § 117.277(a) would require that, if the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 117.251, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility or if we determine that an exemption withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food located at the facility. We tentatively conclude that we will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal.

Proposed § 117.277(b)(1) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within the 10-calendar day period after the hearing is held. We tentatively conclude that it is appropriate to grant the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 117.284 in section XIV.L of this document) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 117.277(b)(2) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. We tentatively conclude that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if we deny the appeal, and is in the interest of public health.

K. Proposed § 117.280—Revocation of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 117.280(a) through (c) would establish that an order to withdraw an exemption applicable to a qualified facility under § 117.5(a) is revoked if:

- (a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- (b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- (c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

We tentatively conclude that an order to withdraw an exemption may be revoked in one of two manners. First, we are proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day time frames. Second, we are proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final

decision expressly confirming the order within the specified time frames will also serve to revoke the order. We tentatively conclude that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

L. Proposed § 117.284—Final Agency Action

Proposed § 117.284 would establish that confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45 (21 CFR § 10.45).

M. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(2) to include part 117, subpart E, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available.

XV. Proposed New Recordkeeping Requirements (Proposed Part 117, Subpart F)

A. Relevant Statutory Provisions

FDA is proposing to create a new Subpart F to establish requirements applying to records that must be established and maintained according to the requirements of this proposed rule. As discussed in section XII.I of this document, section 418 of the FD&C Act prescribes several requirements relevant to recordkeeping. The statutory provisions that are most relevant to proposed subpart F are:

- Section 418(a) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records of monitoring the performance of preventive controls as a matter of routine practice;
- Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility develop a written analysis of the hazards;
- Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain certain records for not less than 2 years. The records identified in section 418(g) include records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions; and
- Section 418(h) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section and that such written plan, together with documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request;
- Section 418(n)(1)(A) of the FD&C Act, which provides, in relevant part, that FDA shall promulgate regulations to establish science-based minimum standards for documenting hazards and documenting the implementation of the preventive controls under this section;
- Section 402(a)(4) of the FD&C Act, which provides that food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- Section 701(a) of the FD&C Act [21 U.S.C. 371(a)], which provides FDA with authority to promulgate regulations for the efficient enforcement of the FD&C Act; and
- Section 361(a) of the Public Health Service Act [42 U.S.C. 264(a)], which provides FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.
- Section 418(l)(2)(B) of the FD&C Act, which requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws.

B. Proposed § 117.301—Records Subject to the Requirements of This Subpart F

Proposed § 117.301(a) would establish that, except as provided by proposed § 117.301(b) and (c), all records required by proposed part 117 would be subject to all requirements of proposed subpart F. FDA tentatively concludes that the requirements in subpart F describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts aid plants and facilities in compliance with the requirements of proposed part 117; and allow plants and facilities to show, and FDA to determine, compliance with the requirements of part 110.

Proposed § 117.301(b) would establish that the requirements of proposed § 117.310 apply only to the written food safety plan and is discussed in more detail in Part D of this section.

Proposed § 117.301(c) would provide that the requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201(e). As discussed in section XIII.A.7 of this document, proposed § 117.201(e) would require that a qualified facility maintain records relied upon to support the self-certification that would be required by § 117.201(a). Such documentation would be directed to the financial basis (and, when applicable, percentage of sales to qualified end users) as well as to food safety practices at the qualified facility, and could range from invoices to a food safety plan to an operating license issued by a state or local authority. Such records would not be expected to satisfy the provisions of proposed § 117.305(b), (d), (e), and (f) (which we discuss in the next section of this document). To make clear that a qualified facility need not comply with provisions that do not apply to its records, we are proposing to specify that those provisions do not apply to such records.

C. Proposed § 117.305—General Requirements Applying to Records

Proposed § 117.305 contains general requirements that would apply to records that would be required under proposed part 117, including the format for required records, the recording of actual values and observations obtained during monitoring, when records must be created, and information that must be included in each record.

1. Proposed § 117.305(a)

Proposed § 117.305(a) would require that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. True copies of records should be of sufficient quality to

detect whether the original record was changed or corrected in a manner that obscured the original entry (e.g., through the use of white-out). Proposed § 117.305(a) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies is consistent with other regulations such as our Good Manufacturing Practices (GMPs) regulation for dietary supplements (§ 111.605(b)) and provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 117.305(a) also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by proposed part 117 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under proposed part 117. However, we request comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under proposed part 117. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which we determined to be the case in the regulation *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (69 FR 71562, December 9, 2004 (the BT records regulation)) For the purposes of the records requirements in the BT records regulation, we concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, we exempted the records from the requirements of part 11 (21 CFR 1.329(b)). We also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR 189.5(c)(7) and 700.27(c)(7), respectively). We also seek comment on whether we should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

2. Proposed § 117.305(b)

Proposed § 117.305(b) would require that records contain the actual values and observations obtained during monitoring. It is neither possible to derive the full benefits of a preventive controls system, nor to verify the operation of the system, without recording actual values and observations to produce an accurate record. Notations that monitoring measurements, such as heat treatment temperatures, are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and temperatures, are vague and subject to varying interpretations and, thus, will not ensure that controls are working properly. In addition, it is not possible to discern a trend toward loss of control without actual measurement values. Proposed § 117.305(b) is consistent with our HACCP regulations for seafood and juice, specifically § 123.6(c)(7) and § 120.12(b)(4), respectively. In addition, our HACCP regulation for juice also requires that records documenting the monitoring of critical control points and their critical limits include recording of actual times, temperatures, or other measurements (§ 120.12(a)(4)(i)). We seek comment on this proposal.

3. Proposed § 117.305(c), (d) and (e)

Proposed § 117.305(c), (d) and (e) would require that records be accurate, indelible, and legible (proposed § 117.305(c)); be created concurrently with performance of the activity documented (proposed § 117.305(d)); and be as detailed as necessary to provide a history of work performed (proposed § 117.305(e)). Proposed § 117.305(c) and (d) would ensure that the records are useful to the owner, operator, or agent in charge of a plant or facility in complying with the requirements of proposed part 117, for example, in documenting compliance with monitoring requirements and verifying compliance with the food safety plan. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of proposed part 117. Proposed § 117.305(e) would provide flexibility to plants and facilities to tailor the amount of detail to the nature of the record. These proposed requirements are consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and our HACCP regulations for seafood and juice. Consistent with the definition of ''monitor'' in proposed § 117.3, the NACMCF guidelines assert that monitoring is a planned sequence of observations or measurements to not only assess whether a CCP is under control but to also produce an accurate record for future use in verification (Ref. 34). The Codex guidelines advise that efficient and accurate record keeping is essential to the application of a HACCP system (Ref. 35). Our HACCP regulations for seafood and juice require that processing and other information be entered on records at the time that it is observed (§§ 123.9(a)(4) and 120.12 (b)(4), respectively).

4. Proposed § 117.305(f)

Proposed § 117.305(f) would require that the records include (1) the name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code, if any. The name and location of the plant or facility and the date and time would allow the owner, operator, or agent in charge of a plant or facility (and, during inspection, an FDA investigator) to assess whether the record is current, to identify when and where any deviation occurred, and to track corrective actions. The signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. Linking a record to a specific product (and, when applicable, the production code) would enable the owner, operator, or agent in charge of a facility to isolate product that has not been processed properly when there has been a problem, thereby limiting the impact of the problem (such as the need to reprocess product or to recall product) to only those lots with the problem.

Proposed § 117.305(f) is consistent with the NACMCF HACCP guidelines and our HACCP regulations for seafood and juice. The NACMCF HACCP guidelines recommend that all records and documents associated with CCP monitoring be dated and signed or initialed by the person doing the monitoring (Ref. 34). Our HACCP regulations for seafood and juice require that all records include the name and location of the processor; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation; and where appropriate, the identity of the product and the production code, if any

(§§ 123.9(a) and 120.12 (b), respectively).

D. Proposed § 117.310—Additional Requirements Applying to the Food Safety Plan

Proposed § 117.310 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion (proposed § 117.310 (a)) and upon any modification (proposed § 117.310(b)). Such a signature would provide direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. Additionally, the signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist. The proposed requirement for signing and dating is consistent with our HACCP regulations for seafood and juice, which require that the HACCP plan be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor and be dated and signed upon initial acceptance; upon any modification; and upon verification of the plan (for seafood) or upon verification and validation (for juice) (§§ 123.6(d) and 120.12 (c) for seafood and juice, respectively).

E. Proposed § 117.315—Requirements for Record Retention

Proposed § 117.315 contains requirements on the length of time records that would be required under proposed part 117 must be retained and allowances for offsite storage of records under certain circumstances.

1. Proposed § 117.315(a) and (b)

Proposed § 117.315(a) would require that all records that would be required by proposed part 117 be retained at the plant or facility for at least 2 years after the date they were prepared. Proposed § 117.315(b) would require that records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.150(a)). Proposed § 117.315(a) and (b) implement subsection 418(g) of the FD&C Act, which requires certain records to be maintained for not less than 2 years. The 2-year timeframe for all records required by proposed part 117 is consistent with the length of time that nonperishable food products, on average, can be expected to be in commercial distribution plus a reasonable time thereafter to ensure that the records are available for verification activities. As we noted in the proposed BT records regulation (68 FR 25188 at 25198, May 9, 2003), according to information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months (68 FR 25188 at 25198). In the final BT records regulation, we concluded that 2 years was the minimum time records related to nonperishable foods for the purpose of identifying immediate previous sources and immediate subsequent recipients should be kept (69 FR 71562 at 71602–3). The 2-year record retention requirement is also consistent with our HACCP regulations for seafood and juice, which both require that records be retained for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products (§§ 123.9(b)(1) and 120.12(d)(1), respectively); and with the requirement in the seafood HACCP regulation that records relating to the general adequacy of equipment or processes, including scientific studies and evaluations, be retained for at least 2 years after their applicability to the product being produced at the facility (§ 123.9(b)(2)). While FDA established shorter records retention requirements for records related to perishable foods in the BT records, seafood HACCP, and juice HACCP regulations, in this case Congress determined and specified in section 418(g) of the FD&C Act that the minimum retention period for the majority of the records required under proposed part 117 for all foods, regardless of perishability, is 2 years. Therefore, FDA tentatively concludes that the same requirement should apply to all records required under this section, regardless of the perishability of the food to which the record relates. This would simplify plants' or facilities' duties in compliance because there would only be one 2-year retention period to apply to any record required under proposed part 117. This 2-year retention period would run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan). We seek comment on this proposal.

2. Proposed § 117.315(c)

Proposed § 117.315(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan would be required to remain onsite. FDA realizes that the proposed requirements for recordkeeping could require some plants or facilities to store a significant quantity of records, and that there may not be adequate storage space in the plant or facility for all of these records. Providing for offsite storage of most records after 6 months would enable a facility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Proposed § 117.315(c) also would provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

Proposed § 117.315(c) is consistent with our HACCP regulations for seafood and juice. Our HACCP regulation for seafood provides for transfer of records if record storage capacity is limited on a processing vessel or at a remote processing site, if the records could be immediately returned for official review upon request (§ 123.9(b)(3)). Our HACCP regulation for juice permits offsite storage of processing records after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review and considers electronic records to be onsite if they are accessible from an onsite location (§ 120.12(d)(2)).

3. Proposed § 117.315(d)

Proposed § 117.315(d) would provide that if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned

to the plant or facility within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods. Proposed § 117.315(d) is consistent with our HACCP regulations for seafood and juice, which provide for transfer of records for facilities closed for prolonged periods (between seasonal packs, in the case of juice) if the records could be immediately returned for official review upon request (§ 123.9(b)(3) and 120.12(d)(3) for seafood and juice, respectively).

F. Proposed § 117.320—Requirements for Official Review

Proposed § 117.320 would require that all records required by proposed part 117 be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request. Proposed § 117.320 implements subsection 418(h) of the FD&C Act and is necessary in order for FDA to determine compliance with the requirements of proposed part 117. Proposed § 117.320 is consistent with our HACCP regulations for seafood and juice, which require that all records required under those rulemakings be available for review and copying at reasonable times (§§ 123.9(c) and 120.12(e), respectively).

Proposed § 117.320 does not explicitly require a facility to send records to the agency rather than making the records available for review at a facility's place of business. FDA requests comment on whether proposed § 117.320 should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically. Obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.

G. Proposed § 117.325—Public Disclosure

Proposed § 117.325 would establish that all records required by proposed part 117 are subject to the disclosure requirements under part 20 of this chapter. FDA's regulations in 21 CFR part 20, the Freedom of Information Act (FOIA) [5 U.S.C. 552], the Trade Secrets Act [18 U.S.C. 1905], and the FD&C Act govern FDA's disclosures of information, including treatment of commercial confidential information (CCI) and trade secret information. Our general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule.

Proposed § 117.325 is consistent with, but framed differently than, the disclosure provisions of the HACCP regulations for seafood and juice (§§ 123.9(d) and 120.12(f), respectively). Proposed § 117.325 is framed similarly to the disclosure provisions for records that must be kept under part 118 (Prevention of Salmonella Enteritidis in Shell Eggs During Production) (the shell egg production rule). Under § 118.10(f), records required by part 118 are subject to the disclosure requirements under part 20.

XVI. FSMA's Rulemaking Provisions

A. Requirements in Section 418(n)(3) of the FD&C Act Regarding Content

1. Requirements of Section 418 of the FD&C Act

Section 418(n)(3) of the FD&C Act specifies that the regulations promulgated under section 418(n)(1)(A) shall:

- ''(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;''
- ''(B) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations;''
- ''(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and''
- ''(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit prevent[ive] controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party.''

2. Section 418(n)(3)(A)

Implementing section 418 through this proposed rule would provide sufficient flexibility to be practicable for all sizes and types of facilities. As discussed in sections II.C and XII of this document, subpart C of the proposed rule (and related requirements) are consistent with HACCP principles. Like HACCP, the preventive controls system proposed in this document would provide flexibility for facilities to tailor their food safety plans to their specific foods and operating conditions. This proposal would allow facilities to establish only those preventive controls that are applicable to their circumstances, and to choose among multiple options wherever there are different ways to significantly minimize or prevent a hazard that is reasonably likely to occur.

In addition, the specific provisions of proposed subpart C (and related requirements) have been designed to maximize their flexibility and practicability wherever it is possible to do so consistently with the requirements of section 418 of the FD&C Act. For example:

- As discussed in section XII.A.2 of this document, proposed § 117.126(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf.
- As discussed in section XII.A.3 of this document, proposed § 117.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would provide flexibility for facilities in the development of their food safety plans.
- As discussed in section XII.C of this document, proposed § 117.135 would provide flexibility with regard to preventive controls by allowing flexibility to establish the parameters and the maximum/minimum values for the selected control.
- As discussed in section XII.C.2 of this document, for process controls, food allergen controls, sanitation controls, and other controls, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 117.135(a).
- As discussed in section XII.H of this document, proposed § 117.155(b) would provide flexibility for the qualified individual to be either an employee of the facility or an individual not employed by the facility (such as individuals associated with universities, trade associations, and consulting companies). Proposed § 117.155(b) would also provide flexibility for the qualified individual to be qualified either through training or job experience.
- As discussed in section XV.C.1 of this document, proposed § 117.305(a) would provide flexibility for mechanisms for keeping records while

maintaining the integrity of the recordkeeping system.

• As discussed in section XV.C.3 of this document, proposed § 117.305(e) would provide flexibility to facilities to tailor the amount of detail in their records to the amount necessary to provide a history of the work performed.

Section 418(m) of the FD&C act also provides us with the authority to exempt certain facilities from the requirements of section 418, or to modify those requirements. As discussed in section X.C.9 of this document, we propose to use this authority to exempt facilities that solely engage in the storage or raw agricultural commodities, other than fruits and vegetables, intended for further distribution or processing (§ 117.5(j)). As discussed in sections X.D and XII.B of this document, we also propose to establish modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment under this authority (proposed §§ 117.7 and 117.206). These proposed modified requirements are specifically designed to be targeted to the specific circumstances of such facilities and therefore to be practicable for such facilities.

We are also proposing to define the terms ''small business'' and ''very small business'' in proposed § 117.3. As discussed in sections VII, X.C.1, and X.C.6 of this document, the proposed rule provides flexibility for small and very small businesses in multiple ways. These special provisions based on business size enhance the flexibility of the proposed rule for businesses of all sizes. First, FDA proposes to allow small and very small businesses more time to come into compliance with Section 418 after the effective date of the rule (2 years and 3 years after the date of publication of the final rule, respectively). FDA expects that this would assist small and very small businesses in making changes that would be required for compliance.

Second, FDA is proposing two exemptions from proposed subpart C that would be available in part based on business size. The proposed exemption for qualified facilities in § 117.5(a) would be available to very small businesses, and to certain other businesses based in part on business size, as set forth in that proposed section. Qualified facilities would be subject instead to the modified requirements in proposed § 117.201, which themselves provide significant flexibility. For example, proposed § 117.201(a) would not specify the form of documentation required for a qualified facility to show that it is in fact a qualified facility, or to demonstrate its own hazard analysis and preventive control system or compliance with state, local, county, or other applicable non-Federal law. Instead, FDA is proposing to accept self-certification of compliance with these requirements, provided that facilities retain the documentation on which they rely and make such documentation available to FDA upon request (§ 117.201(e) and related requirements in proposed subpart F).

In addition, under section 103(c) of FSMA, we have conducted a qualitative risk assessment of certain on-farm activities. Based on that qualitative risk assessment, as discussed in section X.C.6 of this document, we are proposing to exempt facilities that are small or very small businesses engaged only in certain low-risk activity/food combinations from the requirements of section 418. We have identified a significant number of activity/food combinations that we would consider to be low-risk when conducted on-farm by small and very small businesses, set forth in the proposed exemption in § 117.5(g) and (h).

Finally, as discussed in section VII of this document, FDA is proposing to begin enforcement of section 418 of the FD&C Act for all facilities subject to that section only after providing a sufficient time period following publication of the final rule for facilities to come into compliance. Specifically, FDA is proposing that businesses would be required to comply with the final rule 1 year after its publication in the **Federal Register**. Further, FDA is proposing to allow one additional year for small businesses and two additional years for very small businesses to come into compliance with the final rule. Providing additional time for businesses to comply, with the most time given to the smallest businesses, helps to make the regulation practicable for all sizes of facilities.

3. Section 418(n)(3)(B)

In implementing section 418 through this proposed rule, FDA has complied with chapter 35 of title 44, United States code (commonly known as the 'Paperwork Reduction Act' (PRA)), with special attention to minimizing the burden (as defined in section 3502(2) of such Act (44 U.S.C. 3502(2))) on the facility, and collection of information (as defined in section 3502(3) of such Act (44 U.S.C. 3502(3))), associated with the proposed rule. Under section 3502(2) of the PRA, ''burden'' means ''time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency.'' Under section 3502(3) of the PRA, ''collection of information'' means, in relevant part, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for * * * answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons* * *.''

In section XVII of this document, we discuss how this proposed rule complies with the requirements of the PRA. In addition, in implementing section 418 of the FD&C Act, we have paid special attention to minimizing burden and collection of information associated with the proposed rule.

As discussed immediately above in section XVI.A.2, we are proposing requirements that provide significant flexibility for different sizes and types of facilities. By making these requirements flexible enough to be practicable for different sizes and types of facilities, the proposed rule also avoids creating unnecessary information collection burden for facilities, because facilities should be able to tailor their recordkeeping to their specific circumstances while still complying with the requirements of the proposed rule.

In addition, the only requirements we are proposing that constitute collections of information are those that are necessary to meet the requirements of section 418 of the FD&C Act and to efficiently enforce that section. Section 418 requires facilities to establish and maintain certain records, such as the written food safety plan (sections 418(b)(3) and 418(h)), records of monitoring of preventive controls (section 418(g)), records of instances of nonconformance material to food safety (section 418(g)), records of the results of testing and other appropriate means of verification (section 418(g)), records of implementation of corrective actions (section 418(g)), and records of the efficacy of preventive controls and corrective actions (section 418(g)). Section 418(h) also requires facilities to make those records promptly available to FDA upon request. In this proposed rule, FDA has interpreted these requirements in a manner calculated to minimize the associated burden and to minimize recordkeeping requirements beyond those explicitly provided for by the statute to those that are essential to implementation and enforcement of section 418. For example:

• As discussed in section XII.A.3 of this document, FDA is proposing to interpret section 418(h) not to require

written procedures for conducting a hazard analysis or written procedures for establishing preventive controls, thereby avoiding unnecessary recordkeeping burden.

- As discussed in section XII.A.2 of this document, proposed § 117.126 would allow facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical and, thus, would minimize the number of different documents that need to be included in the food safety plan and the recordkeeping burden associated with that plan.
- As discussed in section XII.C.7 of this document, FDA is proposing that written corrective action procedures would not be required for sanitation deviations when the owner, operator, or agent in charge of a facility takes corrective action in accordance with proposed § 117.135(d)(3)(iii), because there would be little benefit in requiring written corrective action procedures for the many sanitation deviations that could occur for which the corrective actions that would need to be taken are very general.
- As discussed in section XII.D.2 of this document, proposed § 117.137 would require facilities to establish recall plans only for foods in which there is a hazard reasonably likely to occur, not for all foods, thereby avoiding unnecessary recordkeeping burden.
- As discussed in section XII.G.6 of this document, FDA is proposing to require written verification procedures only for the frequency of calibration.

4. Section 418(n)(3)(C)

In implementing section 418 through this proposed rule, FDA is proposing to acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.

As discussed in section XII.B.2.a of this document, proposed § 117.130(a)(1) would identify the purpose of the hazard analysis—i.e., to determine whether there are hazards that are reasonably likely to occur. As such, there is a single standard that applies to all covered foods when determining whether preventive controls are required. Proposed § 117.130(a)(1) would require that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. If a food presents no hazard reasonably likely to occur, no preventive controls would need to be established. For foods that present hazards reasonably likely to occur, facilities would be required to establish preventive controls in keeping with one general set of requirements set forth in proposed § 117.135. Thus, proposed subpart C simultaneously acknowledges differences in risk among foods and applies a single standard to all foods subject to that subpart.

In addition, the proposed rule acknowledges differences in risk by establishing exemptions and modified requirements in certain cases. We discuss these proposed exemptions and modified requirements in sections X.C and X.D of this document. The proposed rule would exempt all of the following from proposed subpart C: qualified facilities; activities subject to part 123 (seafood HACCP) and in compliance with that part; activities subject to part 120 (juice HACCP) and in compliance with that part; activities subject to part 113 (LACF) and in compliance with that part with respect to microbiological hazards addressed in that part; manufacturing, processing, packing, or holding of dietary supplements in compliance with part 111 (dietary supplement CGMPs) and section 761 of the FD&C Act (serious adverse event reporting); activities subject to section 419 of the FD&C Act (standards for produce safety); on-farm low-risk activity/food combinations conducted by small or very small businesses engaging only in such activities; alcoholic beverages and limited amounts of non-alcohol prepackaged food at alcohol-related facilities; and facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. In addition, the proposed rule includes modified requirements for facilities solely engaged in the storage of packaged food that is not exposed to the environment. The proposed exemptions and modified requirements implement specific statutory authorities allowing for those exemptions and modifications, indicating that Congress intended that there should be some differences in the requirements for certain foods, certain facilities, and certain activities, depending on risk and on other aspects of the regulatory environment. This proposed rule strikes what FDA considers to be an appropriate balance between acknowledging differences in risk and minimizing the number of separate standards applied to separate foods. We seek comments on our approach.

5. Section 418(n)(3)(D)

This proposed rule would not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventive controls. As discussed in section XII.H of this document, proposed § 117.155(a) would require that a qualified individual conduct (or oversee) certain required activities, and proposed § 117.155(b) would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. The option in proposed § 117.155(b) would provide flexibility to facilities subject to the rule. Providing an option to use a consultant or other third party as the qualified individual to conduct specific functions would not require using a consultant or other third party. These proposed provisions are merely permissive and FDA tentatively concludes that they are consistent with the requirements of section 418(n)(3)(D) of the FD&C Act.

B. Requirements in Section 418(n)(5) of the FD&C Act Regarding Review of Hazard Analysis and Preventive Controls Programs in Existence on the Date of Enactment of FSMA

1. Requirements of Section 418 of the FD&C Act

Section 418(n)(5) of the FD&C Act specifies that, ''[i]n promulgating the regulations [required by section 418(n)(1)(A) of the FD&C Act], the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of [FSMA], including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date.''

2. Overview of FDA's Review of Hazard Analysis and Preventive Controls Programs

FDA has conducted the review of regulatory hazard analysis and preventive control programs and internationally-recognized standards required by section 418(n)(5) of the FD&C Act. To do so, we reviewed the following domestically recognized standards:

- NACMCF's ''Hazard Analysis and Critical Control Point Principles and Application Guidelines'' (Ref. 34);

• FDA's regulation in part 120 (Hazard Analysis and Critical Control Points (HACCP) Systems) for juice;
• FDA's regulation in part 123 (Fish and Fishery Products);
• FSIS' regulation in 9 CFR 417 (Hazard Analysis and Critical and Control Point (HACCP) systems) for meat and poultry products; and
• The Grade ''A'' Pasteurized Milk Ordinance (PMO), specifically the National Conference on Interstate Milk Shipments HACCP alternative found in Appendix K (the PMO HACCP Appendix) (Ref. 37) (Ref. 192).

We also reviewed the following internationally recognized standards:
• The Codex Annex to the Recommended International Code of Practice—General Principles of Food Hygiene on the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Ref. 35);
• The European Parliament and Council of the European Union Regulation (EC) No 852/2004 on the Hygiene of Foodstuffs (the EU regulation) (Ref. 38);
• The requirements for food safety programs in the Australia New Zealand Food Standards Code (the FSANZ Code) (Ref. 39); and
• The Canadian Food Inspection Agency's Food Safety Enhancement Program (the CFIA FSEP) (Ref. 40).

We compared the key features of our proposed requirements to implement section 418 of the FD&C Act (i.e., the proposed requirements that would be established in subpart C of proposed part 117) to the listed domestic and international food safety standards. The key features we compared are:
• Requirement for a food safety plan;
• Requirement for a hazard analysis;
• Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values;
• Requirement for a recall plan;
• Requirement for monitoring procedures;
• Requirement for corrective actions;
• Requirement for verification procedures;
• Requirements applicable to a qualified individual; and
• Requirement for records.

The two most widely applied guidelines are the NACMCF HACCP guidelines and the Codex HACCP Annex. As discussed in section II.C.1 of this document, the NACMCF HACCP guidelines and the Codex HACCP Annex evolved over time, and revisions that NACMCF made to its recommendations in 1992 and 1997 were patterned after changes made in Codex HACCP documents. Thus, the NACMCF HACCP guidelines and the Codex HACCP Annex are similar in their recommendations, although the specific wording is not always identical. In general, domestic standards are patterned after the NACMCF HACCP guidelines and the international standards are patterned after the Codex HACCP Annex.

As noted in section II.C.2 of this document, throughout this document we identify the sections of FSMA applicable to specific proposed provisions and describe how the proposed provisions relate to HACCP principles as established in the NACMCF HACCP guidelines, the Codex HACCP Annex and Federal HACCP regulations for seafood, juice, and meat and poultry. We do not elaborate throughout the document on how the proposed provisions relate to the PMO HACCP Appendix or international standards other than the Codex HACCP Annex (i.e., the EU regulation, the FSANZ Code, and the CFIA FSEP). However, for the purpose of the review required by section 418(n)(5) of the FD&C Act, we discuss all of these standards. We also developed a table showing how the proposed requirements of subpart C compare to the listed domestic and international food safety standards; that table is a reference to this document (Ref. 193).

In other sections of this document, we refer to ''Federal HACCP regulations for seafood, juice, and meat and poultry.'' For the purpose of the review required by section 418(n)(5) of the FD&C Act, we refer to ''domestic'' regulations rather than ''Federal'' regulations.

3. Comparison of Preventive Control Programs

a. Requirement for a food safety plan. Proposed § 117.126 would require that the owner, operator or agent in charge of a facility prepare (or have prepared) and implement a written food safety plan. As discussed in section II.C.3 of this document, NACMCF describes five preliminary tasks in the development of a HACCP plan and seven HACCP principles that apply in implementing a HACCP plan (Ref. 34). The Codex HACCP Annex also describes these five preliminary tasks and seven HACCP principles, although the specific descriptions are not always identical to those in the NACMCF HACCP guidelines (Ref. 35). The domestically recognized standards and all international standards except the FSANZ Code focus on ''HACCP systems'' to control hazards; the FSANZ Code uses the term ''food safety program.''

Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations and the PMO HACCP Appendix require that food establishments as specified in the regulation or standard operate in accordance with the seven HACCP principles. All domestic regulations and the PMO HACCP Appendix require a written HACCP plan (which in this proposed regulation is a food safety plan) whenever the hazard analysis identifies hazards that are reasonably likely to occur. The international standards require, in general, that food establishments as specified in the regulation or standard operate in accordance with the seven HACCP principles as described by Codex. FSANZ requires the food safety program to be written, and CFIA FSEP requires the HACCP plan to be written, but the EU regulation has no explicit requirement that HACCP plans be written.

Proposed § 117.126 would require a written ''food safety plan,'' the term used by FSMA in section 418(h), rather than require a ''HACCP plan.'' Proposed § 117.126 would specify the contents of the food safety plan, including the (1) written hazard analysis; (2) written preventive controls; (3) written monitoring procedures; (4) written corrective action procedures; (5) written verification procedures; and (6) written recall plan. The contents of a written HACCP plan in domestic HACCP regulations are similar but not identical, and include the (1) list of hazards; (2) CCPs; (3) critical limits; (4) monitoring procedures; (5) corrective action procedures; (5) verification procedures; and (6) record-keeping procedures. The PMO HACCP Appendix requires that the HACCP plan include process flow diagrams (also a requirement in the FSIS HACCP regulation for meat and poultry, but not included in the contents of the HACCP plan). FSANZ requires that the food safety program (1) identify hazards; (2) identify where hazards can be controlled and the means: (3) provide for monitoring; (4) provide for corrective actions; (5) provide for regular review for adequacy; and (6) provide for appropriate records of compliance. The CFIA FSEP requires that the HACCP plan include all relevant information needed to conduct the five preliminary steps in addition to the seven HACCP principles. The EU regulation has no explicit requirement for the contents of a HACCP plan other than requiring food business operators to put in place procedures based on the HACCP principles.

b. Requirement for a hazard analysis. Proposed § 117.130 would require that a

hazard analysis be conducted to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine those hazards reasonably likely to occur. As discussed in section XII.B of this document, proposed § 117.130 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex, all domestic HACCP regulations, the PMO HACCP Appendix, and international standards require that a hazard analysis be conducted. Domestic HACCP regulations specify that the outcome is to determine the hazards reasonably likely to occur for the product being produced, which is consistent with the FSANZ requirement that a food business identify the potential hazards that may be reasonably expected to occur in all food handling operations. This outcome is implied by the EU regulation, which requires identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

c. Requirement for preventive controls, including a requirement for control parameters and maximum or minimum values. Proposed § 117.135 would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented. Proposed § 117.135 also would require that preventive controls include, as appropriate to the facility and the food, parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

As discussed in section XII.C of this document, proposed § 117.135 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require the inclusion of CCPs and critical limits in the HACCP plan to control hazards that are identified as reasonably likely to occur. Consistent with the Codex HACCP Annex, the CFIA FSEP and the EU regulation also require the inclusion of CCPs and critical limits in the HACCP plan. FSANZ requires the identification of where, in a food handling operation, each hazard can be controlled, without referring to these as CCPs, and the means of control, but does not specify the establishment of critical limits.

d. Requirement for a recall plan. Proposed § 117.137 would require that a recall plan be established for food in which there is a hazard that is reasonably likely to occur. The CFIA FSEP provides for recall plans as a prerequisite program in the HACCP system. None of the other domestic or international standards include a provision for a recall plan as part of HACCP requirements. Although not part of the Codex HACCP Annex, the Codex GPFH specify that managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market (Ref. 44).

e. Requirement for monitoring procedures. Proposed § 117.140 would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. As discussed in section XII.E of this document, proposed § 117.140 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require monitoring procedures (and the frequency) for CCPs to ensure compliance with critical limits. Consistent with the Codex HACCP Annex, international standards require monitoring, although Codex does not specify that the monitoring system include the frequency of monitoring. The EU regulation requires establishing and implementing effective monitoring procedures at CCPs. The CFIA FSEP requires documented monitoring procedures for each CCP and these must specify any tests, measurements or observations to assess whether the control measure is functioning as intended and the critical limits are met. FSANZ requires that the food safety program provide for the systematic monitoring of controls.

f. Requirement for corrective actions. Proposed § 117.145 would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. As discussed in section XII.F of this document, proposed § 117.145 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix require establishing corrective actions (or corrective action plans) for deviations from established critical limits. Proposed § 117.145 also would require that corrective actions be taken if a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective. This provision of proposed § 117.145 is consistent with corresponding requirements in domestic HACCP regulations for corrective actions when there is no corrective action plan for a specific deviation.

Consistent with the Codex HACCP Annex, international standards require corrective actions. The EU regulation and the CFIA FSEP require establishing corrective actions when monitoring indicates that a critical control point is not under control. FSANZ requires that the food safety program provide for appropriate corrective action when the hazard is found not to be under control. However, only the CFIA FSEP requires that documented deviation procedures specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that the control measure is not functioning as intended or; the critical limits are not met.

g. Requirement for verification procedures. Proposed § 117.150 would require that the owner, operator, or agent in charge of a facility establish specific verification and validation procedures and activities. As discussed in section XII.G of this document, proposed § 117.150 is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex. Consistent with the NACMCF HACCP guidelines, domestic HACCP regulations and the PMO HACCP Appendix require a list of the verification procedures (including validation in the HACCP regulation for juice and the PMO HACCP Appendix), and the frequency of performing these procedures. Consistent with the Codex HACCP Annex, international standards (except FSANZ) require the establishment of verification procedures. The EU regulation requires procedures to verify that the HACCP system is working effectively and the CFIA FSEP requires documentation of verification procedures. FSANZ does not specifically require verification procedures but requires that the food safety program provide for the regular review of the program by the food business to ensure its adequacy.

In addition to validation, proposed § 117.150 would require specific verification activities, i.e., calibration of

process monitoring instruments and verification instruments; records review; and reanalysis. Several of these requirements are found in domestic standards. All domestic HACCP regulations and the PMO HACCP Annex require calibration of monitoring instruments. All domestic HACCP regulations and the PMO HACCP Appendix require record review as a verification activity, and all provide for an annual reanalysis; both of these are specified by the NACMCF guidelines as verification activities. Other than the FSANZ requirement that the food safety program provide for the regular review of the program to ensure its adequacy, the only international standard that provides specific verification activities is the CFIA FSEP, which requires observation of monitoring and corrective actions (which is also a requirement of the FSIS HACCP regulation for meat and poultry) and records review.

h. Requirements applicable to a qualified individual. Proposed § 117.155 would establish the requirements applicable to a qualified individual. We use the term ''qualified individual'' to refer to an individual who is qualified by training or job experience to conduct certain food safety activities as would be specified in proposed subpart C. As discussed in section XII.H of this document, proposed § 117.155 is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Proposed § 117.155 is also consistent with the PMO HACCP Appendix, in which only a person who has met certain qualifications (i.e., through specific training) can carry out certain requirements related to the HACCP system. The NACMCF HACCP guidelines stress the importance of ensuring that individuals have appropriate training to develop and maintain the HACCP system. Similarly, the Codex HACCP Annex emphasizes that training is essential for effective implementation of HACCP. The EU regulation requires ''food business operators'' to ensure that those responsible for the development and maintenance of procedures based on the HACCP principles have received adequate training in the application of the HACCP principles. The CFIA FSEP requires that the individuals responsible for monitoring, deviation and verification procedures have received adequate training.

i. Requirement for records. Proposed § 117.175 would list the records that would required for proposed subpart C, including the food safety plan, records that document the monitoring of preventive controls, records that document corrective actions, records that document verification activities, and records that document applicable training for the qualified individual. Proposed § 117.175 is consistent with the requirements for records in the NACMCF HACCP guidelines, all domestic HACCP regulations and the PMO HACCP Appendix, which require records to include the hazard analysis, HACCP plan, and records of monitoring, corrective actions and verification activities. The Codex HACCP Annex also specifies documentation, including the hazard analysis and CCP and critical limit determination, and records for monitoring, corrective actions and verification procedures. The EU regulation requires records to demonstrate the effective application of the HACCP measures. Similarly, FSANZ requires that the food safety program provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program. The CFIA FSEP requires record keeping to demonstrate the effective application of the critical control points and to facilitate official verifications by the CFIA or other competent authority.

Proposed subpart F would establish requirements that apply to the required records, including requirements for records to be accurate and to include specific information and for record retention. These record-keeping requirements are consistent with the requirements for records in all domestic HACCP regulations, but such details are not found in international standards other than the CFIA FSEP.

XVII. Proposed Removal of 21 CFR Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Proposed part 117 would replace current part 110. Therefore, we are proposing to remove current part 110 after the compliance date for all businesses to be in compliance with the requirements of new part 117. As discussed in section VII of this document, we are proposing that businesses would be required to comply with new part 117 1, 2, or 3 years after the date of publication of the final rule establishing part 117, depending on the size of the business. Thus, we are proposing to remove part 110, 3 years after the date of publication of the final rule.

XVIII. Proposed Conforming Amendments

Several current regulations refer to the requirements of part 110. FDA is proposing a series of amendments so that these current regulations would refer to part 117 as well as part 110. We also are proposing that when part 110 is removed, all references to part 110 be removed from our regulations. The affected regulations are:

- § 106.100(j) and (n) (infant formula records);
- § 114.5 (current good manufacturing practice for acidified foods);
- §§ 120.3, 120.5, and 120.6(b) (definitions, current good manufacturing practice, and sanitation standard operating procedures for juice products subject to the HACCP regulation for juice);
- §§ 123.3, 123.5(a), and 123.11(b) (definitions, current good manufacturing practice, and sanitation control procedures for fish and fishery products subject to the HACCP regulation for seafood);
- § 129.1 (current good manufacturing practice for the processing and bottling of bottled drinking water);
- § 179.25(a) (general provisions for food irradiation); and
- § 211.1(c) (scope of current good manufacturing practice for finished pharmaceuticals).

XIX. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 194). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 194) which is available at *http://www.regulations.gov* (enter Docket No.

FDA–2011–N–0920), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under Section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

F. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) are available to the public in the docket for this proposed rule (Ref. 194).

XX. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXII. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www/regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www/regulations.gov*.

XXIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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191. FDA, ''Food Code 2009: Chapter 3—Food,'' 2009.
192. FDA, ''Grade ''A'' Pasteurized Milk Ordinance (2011 Revision): Appendix K. HACCP Program,'' 2012.
193. FDA Memorandum, ''Comparison of Proposed Subpart C (Hazard Analysis and Risk-Based Preventive Controls) to Various Existing Domestic and International HACCP Based Standards,'' 2012.
194. FDA, ''Preliminary Regulatory Impact Analysis,'' 2012.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 110

Food packaging, Foods.

21 CFR Part 114

Food packaging, Foods, Reporting and recordkeeping requirements.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 120

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.227 is revised to read as follows:

§ 1.227 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Calendar day means every day shown on the calendar.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)),

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)), or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to

consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term ''consumers'' does not include businesses. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between the Food and Drug Administration (FDA) and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under § 1.233(e) another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

■ 3. Section 1.241 is amended by revising paragraph (a) to read as follows:

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 4. Section 1.276 is amended by revising paragraph (b)(9) to read as follows:

§ 1.276 What definitions apply to this subpart?

* * * * *

(b) * * *

(9) *Manufacturer* means the last facility, as that word is defined in § 1.227, that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature. If the food undergoes further manufacturing/processing that exceeds an activity of a de minimis nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

* * * * *

■ 5. Section 1.328 is amended by removing the definition for ''Act'' and by alphabetically adding definitions for ''Harvesting'', ''Mixed-type facility'', and ''Packing'', and revising the definitions for ''Farm'', ''Food'', ''Holding'', ''Manufacturing/processing'', and ''Packaging'' to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity,

as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Holding means storage of food. Holding facilities include: Warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

* * * * *

Packaging (when used as a noun) means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)).

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 6. Section 1.361 is revised to read as follows:

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

■ 7. Section 1.363 is revised to read as follows:

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 8. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 9. Section 16.1 is amended by numerically adding the following entry in paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 117.251 through 117.284 (part 117, subpart E), relating to withdrawal of an exemption applicable to a qualified facility.

* * * * *

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

■ 10. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: 21 U.S.C. 321,350a, 371.

■ 11. Section 106.100 is amended by revising the fourth sentence of paragraph (j) and paragraph (n) to read as follows:

§ 106.100 Records.

* * * * *

(j) * * * Records of audits shall include the information and data necessary for a determination as to whether the manufacturer complies with the current good manufacturing practices and quality procedures identified in parts 106, 107, 109, 110, 113, and 117 of this chapter. * * *

* * * * *

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, 113, and 117 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant

formula or 3 years from the date of manufacture, whichever is greater.

* * * * *

PART 110—[REMOVED AND RESERVED]

■ 12. Part 110 is removed and reserved [A DATE WILL BE ADDED 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

PART 114—ACIDIFIED FOODS

■ 13. The authority citation for 21 CFR part 114 continues to read as follows:

Authority: 21 U.S.C. 342, 371,374; 42 U.S.C. 264.

■ 14. Revise § 114.5 to read as follows:

§ 114.5 Current good manufacturing practice.

(a)(1) The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in parts 110 and 117 of this chapter, apply in determining whether an article of acidified food is adulterated:

(2) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food, or

(3) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(b) [Reserved]

■ 15. Add part 117 to read as follows:

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart A—General Provisions

Sec.
117.1 Applicability and status.
117.3 Definitions.
117.5 Exemptions.
117.7 Applicability of subparts C and D to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

Subpart B—Current Good Manufacturing Practice

117.10 Personnel.
117.20 Plant and grounds.
117.35 Sanitary operations.
117.37 Sanitary facilities and controls.
117.40 Equipment and utensils.
117.80 Processes and controls.
117.93 Warehousing and distribution.
117.110 Defect Action Levels

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

117.126 Requirement for a food safety plan.
117.130 Hazard analysis.
117.135 Preventive controls for hazards that are reasonably likely to occur.
117.137 Recall plan for food with a hazard that is reasonably likely to occur.
117.140 Monitoring.
117.145 Corrective actions.
117.150 Verification.
117.155 Requirements applicable to a qualified individual.
117.175 Records required for subpart C.

Subpart D—Modified Requirements

117.201 Modified requirements that apply to a qualified facility.
117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.
117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.
117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.
117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.
117.264 Procedure for submitting an appeal.
117.267 Procedure for requesting an informal hearing.
117.270 Requirements applicable to an informal hearing.
117.274 Presiding officer for an appeal and for an informal hearing.
117.277 Time frame for issuing a decision on an appeal.
117.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.
117.284 Final agency action.

Subpart F—Requirements Applying to Records That Must be Established and Maintained

117.301 Records subject to the requirements of this subpart F.
117.305 General requirements applying to records.
117.310 Additional requirements applying to the food safety plan.
117.315 Requirements for record retention.
117.320 Requirements for official review.
117.325 Public disclosure.

Subpart G—[Reserved]

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 117.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether a food is adulterated:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of part 117 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(uu)).

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 117.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Acid foods or *acidified foods* means foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to

effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Cross-contact means the unintentional incorporation of a food allergen into a food.

Environmental pathogen means a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located;

(i) In the same State as the qualified facility that sold the food to such restaurant or establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards.

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Should is used to state recommended or advisory procedures or identify recommended equipment.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part 117, a business employing fewer than 500 persons.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

Option 1 for Definition of ''Very Small Business''

Very small business means, for purposes of this part 117, a business that has less than $250,000 in total annual sales of food, adjusted for inflation.

Option 2 for Definition of ''Very Small Business''

Very small business means, for purposes of this part 117, a business that has less than $500,000 in total annual sales of food, adjusted for inflation.

Option 3 for Definition of ''Very Small Business''

Very small business means, for purposes of this part 117, a business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.

Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subpart C of this part does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 117.201.

(b) Subpart C of this part does not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 123 of this chapter with respect to such activities.

(c) Subpart C of this part does not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 120 of this chapter with respect to such activities.

(d)(1) Subpart C of this part does not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subpart C does not apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g) Subpart C of this part does not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act

that the business conducts are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership— i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(1) Hard candy, fudge, taffy and toffee;

(2) Cocoa beans and coffee beans (raw and roasted);

(3) Cocoa products;

(4) Grains and grain products;

(5) Honey (raw and pasteurized);

(6) Intact fruits and vegetables (for purposes of paragraph (g) and paragraph (h) of this section only, ''intact fruits and vegetables'' refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts);

(7) Jams, jellies and preserves;

(8) Maple sap for syrup and maple syrup;

(9) Peanuts and tree nuts;

(10) Soft drinks and carbonated water;

(11) Sugar beets, sugarcane, and sugar;

(h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following:

(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Boiling/evaporation of maple sap to make maple syrup;

(iii) Chopping raw peanuts and raw tree nuts;

(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);

(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);

(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);

(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);

(viii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(ix) Making sugar from sugar beets and sugarcane; and

(x) Salting raw peanuts and raw tree nuts.

(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:

(i) Artificial ripening of intact fruits and vegetables;

(ii) Chopping peanuts and tree nuts;

(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);

(iv) Cooling intact fruits and vegetables using cold air;

(v) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;

(vi) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);

(vii) Fermenting cocoa beans and coffee beans;

(viii) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);

(ix) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

(x) Making hard candy, fudge, taffy, and toffee;

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making honey;

(xiii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);

(xiv) Making maple syrup;

(xv) Making soft drinks and carbonated water;

(xvi) Making sugar from sugar beets and sugarcane;

(xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;

(xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xix) Salting peanuts and tree nuts;

(xx) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;

(xxi) Sifting grains and grain products;

(xxii) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;

(xxiii) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);

(xxiv) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

(i)(1) Subpart C of this part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subpart C of this part does not apply with respect to food other than alcoholic beverages at a facility

described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k) Subpart B of this part does not apply to ''farms'' (as defined in § 1.227 of this chapter), activities of ''farm mixed-type facilities'' (as defined in § 1.227) that fall within the definition of ''farm,'' or the holding or transportation of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 117.7 Applicability of subparts C and D to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(b) A facility solely engaged in the storage of packaged food that is not exposed to the environment is subject to the modified requirements in § 117.206 of subpart D of this part.

Subpart B—Current Good Manufacturing Practice

§ 117.10 Personnel.

The plant management must take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 117.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material, and to reduce the potential for cross-contact. The potential for cross-contact and contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations

in which cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces and for cross-contact.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 117.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

(1) Food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant should be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials.

(f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.

§ 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) *Water supply.* The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to

flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal must be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§ 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained.

(2) The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents.

(6) Food-contact surfaces must be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and cross-contact.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food must be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 117.80 Processes and controls.

(a) *General.* (1) All operations in the manufacturing, processing, packing and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) All reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if permissible, treated or processed to eliminate the contamination.

(b) *Raw materials and ingredients.* (1) Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to cross-contact, contamination, or deterioration of food.

(2) Raw materials and ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

(4) Raw materials, ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against cross-contact and contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and ingredients must be kept frozen. If

thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated.

(7) Liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.

(8) Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.

(c) *Manufacturing operations.* (1) Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food. Food transported by conveyor must be protected against cross-contact and contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.

(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. Food should be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against cross-contact and contamination.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.

§ 117.110 Defect action levels.

Natural or unavoidable defects in food for human use that present no health hazard:

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods when it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or the requirements in this part that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Requirement for a food safety plan.

(a) *Food safety plan.* The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) *Contents of a Food Safety Plan.* The food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 117.140(a);

(4) The written corrective action procedures as required by § 117.145(a)(1);

(5) The written verification procedures as required by § 117.150(e); and

(6) The written recall plan as required by § 117.137(a).

(c) *Qualified individual.* The food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

§ 117.130 Hazard analysis.

(a) *Requirement for a hazard analysis.* (1) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur.

(2) The hazard analysis must be written.

(b) *Hazard identification.* The hazard identification must consider hazards that may occur naturally or may be unintentionally introduced, including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance;

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;

(3) Physical hazards; and

(4) Radiological hazards.

(c) *Hazard evaluation.* (1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

(2) The hazard analysis must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

(3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage, and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors.

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.

For hazards indentified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Preventive controls must be written.

(c) Preventive controls must include, as appropriate to the facility and the food:

(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods, and

(2) The maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

(d) Preventive controls must include, as appropriate:

(1) *Process controls.* Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur.

(2) *Food allergen controls.* Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from cross-contact, including during storage and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) *Sanitation controls.* (i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(ii) The owner, operator or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

(iii) The owner, operator, or agent in charge of a facility is not required to follow the corrective actions established in § 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(3)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) of this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

(4) *Recall plan.* Recall plan as required by § 117.137.

(5) *Other controls.* Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

(i) Monitoring as required by § 117.140;

(ii) Corrective actions as required by § 117.145; and

(iii) Verification as required by § 117.150.

(2) The recall plan established in § 117.137 is not subject to the requirements of paragraph (e)(1) of this section.

§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.

For food with a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 117.140 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.

(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with § 117.150(d)(5)(i).

§ 117.145 Corrective actions.

(a) *Corrective action procedures.* (1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(ii) All affected food is evaluated for safety; and

(iii) All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) *Corrective action in the event of an unanticipated problem.* If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (a)(2)(iii) of this section; and

(2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.

(c) *Documentation.* All corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

§ 117.150 Verification.

(a) *Validation.* Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed by (or overseen by) a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The food allergen controls in § 117.135(d)(2);

(ii) The sanitation controls in § 117.135(d)(3); and

(iii) The recall plan in § 117.137.

(b) *Monitoring.* The owner, operator, or agent in charge of a facility must verify that monitoring is being conducted, as required by § 117.140.

(c) *Corrective actions.* The owner, operator, or agent in charge of a facility must verify that appropriate decisions about corrective actions are being made, as required by § 117.145 and § 117.135(d)(3)(ii).

(d) *Implementation and effectiveness.* The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as appropriate to the facility and the food:

(1) Calibration of process monitoring instruments and verification instruments; and

(2) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within a week after the records are made.

(ii) Records of calibration within a reasonable time after the records are made.

(e) *Written procedures for verification activities.* As appropriate to the facility and the food, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

(f) *Reanalysis.* (1) The owner, operator, or agent in charge of a facility must:

(i) Conduct a reanalysis of the food safety plan;

(A) At least once every 3 years;

(B) Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;

(C) Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;

(D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and

(E) Whenever a preventive control is found to be ineffective.

(ii) Complete such reanalysis and implement any additional preventive controls needed to address the hazard

identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production; and

(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

(2) The reanalysis must be performed (or overseen) by a qualified individual.

(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

(g) *Documentation.* All verification activities taken in accordance with this section must be documented in records.

§ 117.155 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(c));

(2) Validation of the preventive controls (§ 117.150(a)(1));

(3) Review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 117.150(d)(2)); and

(4) Reanalysis of the food safety plan (§ 117.150(f)(2)).

(b) To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.175 Records required for subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan.

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation,

(ii) Monitoring,

(iii) Corrective actions,

(iv) Calibration of process monitoring and verification instruments,

(v) Records review, and

(vi) Reanalysis; and

(5) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

(a) *Documentation to be submitted.* A qualified facility must submit the following documentation to the FDA:

(1) Documentation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(b) *Procedure for submission.* The documentation required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) *Electronic submission.* To submit electronically, go to *http://www.access.fda.gov* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* To submit documents in a paper format or in an electronic format on a CD–ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

(c) *Frequency of submission.* The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a ''qualified facility.''

(d) *Notification to consumers.* A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (c)(1) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(e) *Records.* (1) A qualified facility must maintain those records relied upon to support the documentation required by § 117.201(a).

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food that requires time/temperature control to

significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) If there is a problem with the temperature controls for such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(b) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) If FDA determines that an exemption applicable to a qualified facility under § 117.5(a) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(h) The name and the title of the FDA representative who approved the order.

§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) The owner, operator, or agent in charge of a qualified facility that receives an order under § 117.251 to withdraw an exemption applicable to that facility under § 117.5(a) must either:

(1) Comply with applicable requirements of this part within 60 calendar days of the date of the order; or

(2) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 117.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order.

§ 117.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 117.5(a), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 117.267.

§ 117.267 Procedure for requesting an informal hearing.

(a) If the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 117.270 Requirements applicable to an informal hearing.

If the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 117.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 117.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 117.277 Time frame for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 117.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) is revoked if:

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 117.284 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 117.301 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) The requirements of § 117.310 apply only to the written food safety plan.

(c) The requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201(e).

§ 117.305 General requirements applying to records.

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(b) Contain the actual values and observations obtained during monitoring;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 117.310 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility:

(a) Upon initial completion; and

(b) Upon any modification.

§ 117.315 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.150(a));

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 117.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

§ 117.325 Public disclosure.

Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart G—[Reserved]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

■ 16. The authority citation for 21 CFR part 120 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241.

■ 17. Amend § 120.3 by revising the first sentence of the introductory text to read as follows:

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. * * *

* * * * *

■ 18. Revise § 120.5 to read as follows:

§ 120.5 Current good manufacturing practice.

Except as provided by § 117.5(c), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

■ 19. Amend § 120.6 by revising the first sentence of paragraph (b) to read as follows:

§ 120.6 Sanitation standard operating procedures.

* * * * *

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 and in subpart B of part 117 of this chapter that are appropriate both to the plant and to the food being processed. * * *

* * * * *

PART 123—FISH AND FISHERY PRODUCTS

■ 20. The authority citation for 21 CFR part 123 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264.

■ 21. Revise the first sentence of the introductory text in § 123.3 to read as follows:

§ 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard, and manufacturing/processing in parts 110 and 117 do not govern such terms where used in this part. * * *

* * * * *

■ 22. Revise paragraph (a) of § 123.5 to read as follows:

§ 123.5 Current good manufacturing practice.

(a) Except as provided by § 117.5(b), parts 110 and 117 of this chapter apply in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

* * * * *

■ 23. Amend § 123.11 by revising the introductory text of paragraph (b) to read as follows:

§ 123.11 Sanitation control procedures.

* * * * *

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 and in subpart B of part 117 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

* * * * *

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

■ 24. The authority citation for 21 CFR part 129 continues to read as follows:

Authority: 21 U.S.C. 342, 348, 371, 374; 42 U.S.C. 264.

■ 25. Revise § 129.1 to read as follows:

§ 129.1 Current good manufacturing practice.

The applicable criteria in parts 110 and 117 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

■ 26. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 27. Revise paragraph (a) of § 179.25 to read as follows:

§ 179.25 General provisions for food irradiation.

* * * * *

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of parts 110 and 117 of this chapter and other applicable regulations.

* * * * *

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 28. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 29. Amend § 211.1 by revising the last sentence in paragraph (c) to read as follows:

§ 211.1 Scope.

* * * * *

(c) * * * Therefore, until further notice, regulations under parts 110 and 117 of this chapter, and where applicable, parts 113 to 129 of this chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

Although the proposed rule that is the subject of this document does not include provisions for environmental monitoring or finished product testing, we believe that these regimes can play a critical role in a modern food safety system. In sections XII.J.2 and XII.J.3 of the preamble of this document, we request comment on when and how these types of testing are an appropriate means of implementing the statutory directives set out in section 418 of the FD&C Act. In this Appendix, we provide background material on these testing measures.

I. The Role of Testing as a Verification Measure in a Modern Food Safety System

A. Verification of Preventive Controls

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 34) (Ref. 110). Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. 111) (Ref. 112). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. Although testing may be conducted for biological, chemical, physical or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. We focus more of our discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating food; thus such verification testing is important in preventing contamination in food, whereas verification testing of raw materials, ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections I.C, I.E, and I.F of this Appendix, microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate RTE food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the food.

Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. For example, a dry blending operation, e.g., for spices and seasonings, often verifies its supplier controls by testing incoming ingredients before use (as discussed in section I.C of this Appendix) and periodically sampling and testing finished products. If all the ingredients being blended had been treated to adequately reduce hazards such as *Salmonella spp.,* a dry blending operation generally does less testing to verify supplier controls than if this were not the case. (We use the term ''adequately reduce'' (which is a term used in some of our guidance documents) (Ref. 6) (Ref. 156) to mean the same as ''significantly minimize or prevent'' as described in section 418 of the FD&C Act or ''prevent, eliminate or reduce to an acceptable level'' as used in our seafood and juice HACCP regulations. All these terms mean to reduce a hazard to an extent that it is not reasonably likely to cause illness or injury.) A dry blending operation generally does not test incoming ingredients if the facility treats the blended materials to ensure adequate reduction of pathogens but sometimes tests finished product to verify preventive controls have been effective. A dry blending operation also sometimes uses environmental monitoring to verify that sanitation controls to significantly minimize or prevent the potential for environmental pathogens to contaminate the blended materials have been effective.

For acidified canned vegetables in which a lethal process is delivered in the final package, microbial testing of incoming ingredients and of finished product provides little benefit as a verification activity (although it would be used in process validation); however, facilities producing such products sometimes conduct periodic testing of incoming ingredients for pesticides as an appropriate supplier verification activity.

B. Scientifically Valid Sampling and Testing

Consistent with our previous discussion of the term ''scientifically valid'' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12158 at 12198), we use the term ''scientifically valid'' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be scientifically

valid if they are to provide assurance that preventive controls are effective.

C. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility. The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

- The hazard and its association with the raw material or ingredient;
- The likelihood that the consumer would become ill if the hazard were present in the raw material or ingredient;
- How that raw material or ingredient will be used by the receiving facility (e.g., the effect of processing on the hazard); and
- The potential for contamination of the facility's environment with the hazard in the raw material or ingredient.

Testing a raw material or ingredient occurs more frequently when there is a history of the hazard in the raw material or ingredient, e.g., from a specific supplier or from the country of origin. Once a facility has developed a relationship with a supplier and there is a history of tests negative for the hazard, the frequency is often reduced.

Testing a raw material or ingredient is more useful, and a facility generally tests a raw material or ingredient more frequently, when the raw material or ingredient contains a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. However, when a hazard that the receiving facility has identified as reasonably likely to occur in a raw material or ingredient is one for which the receiving facility has preventive controls that significantly minimize or prevent the hazard, testing generally is less frequent. An exception to this general paradigm is when the process control depends on the amount of the hazard present in the raw material or ingredient (e.g., when the process control is effective at eliminating 100 microorganisms per gram of ingredient, but not 1,000 microorganisms per gram of ingredient) and there is a need to verify that the hazard is not present in amounts that would render the process control ineffective. A receiving facility often finds that testing of raw materials or ingredients is most useful, and generally tests more frequently, when the receiving facility does not have a process that would significantly minimize the hazard and is relying on preventive controls earlier in the supply chain to significantly minimize or prevent the hazard in the raw material or ingredient, as in a bagged salad facility or a dry-mix operation producing, for example, spice blends or trail mix. In such situations, the testing is conducted to verify the preventive controls used to ensure that hazards in the raw material or ingredient have been significantly minimized or prevented.

The frequency of the testing conducted by a facility generally depends in part on the likelihood and severity of illness to the consumer if the hazard were present, the ability of supplier controls to significantly minimize or prevent the hazard in the raw material or ingredient, the practicality of testing to detect the hazard, and other factors. For example, a facility generally tests a raw material or ingredient more frequently from a supplier that does not have a kill step for *Salmonella* spp. in shelled nutmeats compared to a supplier that steam treats the nuts to kill *Salmonella spp.* As another example, if a facility tests a raw material or ingredient as part of its food safety program for salad greens, the facility is more likely to test more frequently for *E. coli* O157:H7 than for other Shiga-toxin producing *E. coli* (pathogenic *E. coli* that produce the same toxin as *E. coli* O157:H7 but are less likely to cause severe illness (Ref. 195)), based on both the severity of the illness to the consumer and practical problems with testing fresh produce for pathogenic strains of Shiga-toxin producing *E. coli.* Where a raw material or ingredient could introduce an environmental pathogen such as *Salmonella spp. or L. monocytogenes* to the facility (e.g., raw nuts or soy powder for *Salmonella spp.;* chopped celery to be used in a salad for *L. monocytogenes*), a facility generally tests the raw material or ingredient more frequently to verify that supplier controls for the raw material or ingredient minimize to the extent possible the potential for a contaminated raw material or ingredient to introduce the environmental pathogen to the facility's environment.

As discussed in section I.F of this Appendix, there are limitations to testing food. Thus, as with other testing, raw material or ingredient testing is rarely the sole basis for making a determination on the safety of a raw material or ingredient.

D. Verification of Sanitation Controls To Significantly Minimize or Prevent the Potential for an Environmental Pathogen To Contaminate Food

1. Environmental Pathogens in Food

As discussed in section II.D of the preamble of this document, food can become contaminated with pathogenic microorganisms at many different steps in the farm-to-table continuum. Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section X.B of the preamble of this document, proposed § 117.3 would define the term ''environmental pathogen'' to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently involved in the contamination of foods leading to foodborne illness are *Salmonella* spp. and *L. monocytogenes.*

2. *Salmonella spp.* as an Environmental Pathogen

We discuss *Salmonella* spp. in section II.D.2.a of the preamble of this document. *Salmonella* has been isolated from a variety of foods and it can get into food by a variety of mechanisms (see section II.D of the preamble of this document). Our focus here is on *Salmonella* contamination from the environment (discussed further in section I.D.2 of this Appendix), particularly as a hazard associated with low-moisture foods (Ref. 145) (Ref. 179). Low-moisture foods include cereal, peanuts, nuts, nut butters (including peanut butter), spices, dried herbs, milk powder, chocolate and many other foods. Although *Salmonella* outbreaks from low-moisture foods are less common than from foods such as eggs and produce, several such outbreaks in the last decade have involved hundreds of illnesses (Ref. 145). The low-moisture foods causing outbreaks included cereal, raw almonds, dried snacks, spices, and peanut butter (Ref. 145) (Ref. 196). Chocolate also has been a source of outbreaks from *Salmonella* spp., although none in the U.S. in recent years (Ref. 145). Dried dairy products, such as milk and whey, also present a risk of contamination with *Salmonella* spp. from the environment (Ref. 197). A review of FDA recall data from 1970 to 2003 showed there were 21 recalls of spices and herbs contaminated with *Salmonella* spp. (Ref. 198). Almost half of the 86 primary RFR entries reported in the first RFR Annual Report due to finding *Salmonella* spp. were from low-moisture foods (Ref. 60).

3. *Listeria monocytogenes* as an Environmental Pathogen

We discuss *L. monocytogenes* in section II.D.2.a of the preamble of this document. As discussed in that section, the FDA/FSIS Lm RA shows that the risk of illness from *L. monocytogenes* increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of *L. monocytogenes* than from those that do not (Ref. 56). A key finding of the risk assessment released by FAO in 2004 was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. 54). Refrigerated foods present a greater risk from *L. monocytogenes* because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if *L. monocytogenes* is present in a food. Growth of *L. monocytogenes* does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with *L. monocytogenes* is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from *L. monocytogenes* in that food increases. As discussed in section II.D.1 of the preamble of this document, contamination of RTE food with *L. monocytogenes* from the environment is common and, thus, targeted preventive controls to significantly minimize or prevent *L. monocytogenes* contamination of RTE foods are warranted.

4. Environmental Pathogens in the Plant Environment

Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects (Ref. 145) (Ref. 179) (Ref. 199) (Ref. 144) (Ref. 185). Once in the facility, environmental

pathogens can be a source of contamination of food. Environmental pathogens may be transient strains or resident strains (Ref. 145) (Ref. 179) (Ref. 199). Transient strains are environmental pathogens that contaminate a site in the facility where they can be eliminated by normal cleaning and sanitizing (Ref. 199). Transient strains tend to vary over time within a facility, e.g., they will be found in different areas and the specific strain will differ. Resident strains are environmental pathogens that contaminate a site in the facility that is difficult to clean and sanitize with normal cleaning and sanitizing procedures and, thus, these strains become established in what is referred to as a ''niche'' or harborage site (Ref. 145) (Ref. 179) (Ref. 199) (Ref. 144) (Ref. 185) (Ref. 200). The finding of the same specific strain multiple times in a facility often indicates a resident strain.

If a harborage site contains nutrients (i.e., food) and water and is exposed to a temperature that falls within the growth range of the environmental pathogen, the pathogen can multiply, which increases the chance that it will be transferred to other sites (including food-contact surfaces) and to food. Transfer can occur by people (e.g., if a person touches the contaminated site and then touches other objects, or tracks the pathogen from the contamination site to other sites on shoes), by equipment (e.g., if the pathogen is picked up by the wheels of a cart or forklift and is transferred to other locations), by water (e.g., water that contacts the harborage site is splashed onto other areas, including equipment, or aerosols containing the pathogen transfer it to other areas) or by air (dissemination of contaminated dust particles by air handling systems) (Ref. 145) (Ref. 179) (Ref. 200) (Ref. 144). Such transfer mechanisms from harborage sites can result in intermittent contamination of food-contact surfaces and food over long periods of time, often with the same strain of the pathogen (Ref. 145) (Ref. 199) (Ref. 200) (Ref. 201).

5. Contamination of Food With *Salmonella* spp. From the Plant Environment

As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen *Salmonella* spp. Such contamination has led to recalls and to outbreaks of foodborne illness.

In 1998, a breakfast cereal product was implicated in an outbreak, due to *Salmonella* Agona, that caused 409 illnesses and one death in 23 states (Ref. 201) (Ref. 202) (Ref. 203). During the outbreak investigation, *Salmonella* was isolated from various locations in the plant, including the floor, processing equipment, and the exhaust system of the implicated processing line (Ref. 201). In 2008, the same *Salmonella* Agona strain was again implicated in an outbreak linked to a similar cereal product from the same manufacturing facility (Ref. 204). In the 2008 outbreak, the same strain was isolated from patients, cereal and the plant environment (Ref. 204).

In 2006–2007, a commercial brand peanut butter contaminated with *Salmonella* Tennessee caused 715 illnesses and 129 hospitalizations (Ref. 62). FDA isolated *Salmonella* Tennessee from 13 unopened jars of peanut butter with production dates ranging from August 2006 to January 2007 and from two plant environmental samples (Ref. 63).

During the years 2008 through 2010, there were three large recalls of foods containing ingredients contaminated with *Salmonella* spp. where FDA's investigation identified insanitary conditions at the facility that manufactured the ingredient and detected *Salmonella* spp. in the plant environment (Ref. 19) (Ref. 23) (Ref. 66) (Ref. 67) (Ref. 68) (Ref. 69) (Ref. 205) (Ref. 155) (Ref. 206). In 2008–2009, an outbreak was linked to *Salmonella* Typhimurium in peanut butter and peanut paste (Ref. 66) (Ref. 67) (Ref. 205). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. 67). Implicated foods included contaminated peanut butter consumed at institutional settings and crackers made with the contaminated peanut butter as an ingredient (Ref. 66) (Ref. 67). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 19) (Ref. 68) (Ref. 69). Several strains of *Salmonella* spp. were found in multiple products and in the plant environment (Ref. 68). This outbreak led to the recall of more than 3900 products containing peanut-derived ingredients (Ref. 20).

In 2009, USDA detected *Salmonella* spp. in a powdered dairy shake and FDA began an investigation of the suppliers of ingredients used to manufacture the product. The inspection of the supplier of one of the ingredients uncovered insanitary conditions that resulted in the recall of multiple ingredients manufactured by that supplier, including instant nonfat dried milk and whey proteins, produced over a 2-year period (Ref. 155). During its investigation of the supplier's facility, FDA identified several strains of *Salmonella* spp. on food-contact and non-food-contact surfaces and in other areas of the plant environment, as well as a number of sanitation deficiencies (Ref. 206).

In 2010, FDA received a report through the RFR of *Salmonella* contamination of hydrolyzed vegetable proteins that a company purchased as an ingredient. Both the company that submitted the report and FDA found multiple *Salmonella*-positive samples collected from the plant environment, including food-contact surfaces. FDA found numerous sanitation deficiencies during its inspection of the production facility. There were no reports of illness associated with the contamination, but multiple product recalls resulted (Ref. 23).

6. Contamination of Food With *L. monocytogenes* From the Plant Environment

As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen *L. monocytogenes.* Such contamination has led to recalls and to outbreaks of foodborne illness.

Between October 2008 and March 2009, eight cases of listeriosis from five states were linked to Mexican-style cheese that was likely contaminated post-pasteurization (Ref. 72). The outbreak strain was isolated from product and from a vat gasket in a post-pasteurization section of the processing line.

In October 2010, the Texas Department of State Health Services ordered a fresh-cut produce facility to stop processing after laboratory tests of chopped celery indicated the presence of *L. monocytogenes* (Ref. 207). The testing was done as part of an investigation of 10 cases of listeriosis, six of which were linked to chopped celery from the facility. Texas Department of State Health Services and FDA inspectors found sanitation deficiencies at the plant (Ref. 207) (Ref. 208) and suggested that the *L. monocytogenes* in the chopped celery may have contaminated other produce. FDA laboratory testing found *L. monocytogenes* in multiple locations in the plant environment, including on food-contact surfaces; the DNA fingerprint of the *L. monocytogenes* in the FDA samples matched the DNA fingerprint of the clinical cases reported by the Texas Department of State Health Services (Ref. 209).

In 2011, an outbreak of listeriosis from cantaloupes was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (Ref. 79) (Ref. 80). The outbreak appears to have occurred due to a combination of factors, including pooled water on the floor of the facility (which was also difficult to clean), poorly designed equipment (not easily cleaned and sanitized) that was previously used for a different commodity, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 79).

There have been several outbreaks in which meat or poultry products produced in FSIS-inspected establishments were contaminated with *L. monocytogenes* from the plant environment (Ref. 210), and much of our understanding of sources of *L. monocytogenes* in the plant environment, as well as appropriate ways to control this organism, has come from the efforts of FSIS and the meat and poultry industry to control this hazard in FSIS-inspected establishments (Ref. 185). For example, harborage sites such as hollow rollers, rubber seals, close-fitting metal-to-metal spaces in equipment such as slicers, and on-off switches of equipment were identified in meat and poultry establishments. The increased risk of contamination resulting from construction, and the importance of control of traffic and water in the RTE area also became widely known as a result of investigations at meat and poultry establishments (Ref. 144) (Ref. 185).

Outbreaks of listeriosis resulting from environmental contamination have also occurred in other countries. For example, an outbreak of listeriosis in Finland in 1999 was associated with butter (Ref. 211). The outbreak strain was isolated from the manufacturing facility, including from the

packaging machine and the floor (Ref. 211). An outbreak of listeriosis in 2009 in Austria and Germany was associated with acid curd cheese; the outbreak strain was found in the production facility (Ref. 212).

Many foods without a known association with illnesses have been recalled due to the presence of *L. monocytogenes* (Ref. 188) (Ref. 189) (Ref. 190) (Ref. 213). There is also an extensive body of literature on isolation of *L. monocytogenes* in the food processing environment. Information on the environment as a source of *Listeria* has been available for many years. For example, in a 1989 study involving 6 different types of food plants (frozen food, fluid dairy, cheese, ice cream, potato processing, and dry food), drains, floors, standing water, food residues, and food-contact surfaces were found to be positive (Ref. 214). No finished foods were tested, but the authors concluded that food production environments could be the source of contamination for foods that have received listericidal treatments and that measures should be taken to prevent survival and growth of these organisms in food environments (Ref. 214).

Listeria testing in 62 dairy facilities during 1987–1988 (including facilities producing fluid milk, frozen product, butter, processed cheese, natural cheese and dry products) found *Listeria* in a variety of locations, including packaging equipment, conveyors, coolers, drains and floors (Ref. 215). *Listeria* was detected more frequently in wet locations, including drains, conveyors and floors (Ref. 215). Pritchard and co-workers also examined 21 dairy processing environments for *Listeria* and found 80 of 378 sites positive for *Listeria* spp. (Ref. 216). Sites positive for *L. monocytogenes* included holding tanks, table tops, conveyor/chain systems, a milk filler and a brine pre-filter machine (Ref. 216).

The packaging machine was found to be the main problem with *L. monocytogenes* that persisted in an ice cream plant in Finland for several years and occasionally contaminated finished product (Ref. 217). A volumetric doser was found to be the source of *L. monocytogenes* in sauces produced in a fresh sauce production plant in Italy (Ref. 218), and slicers and conveyor belts were found to contribute to contamination of sandwiches in a Swiss sandwich producing plant (Ref. 219). *L. monocytogenes* also has been found on tables, water hoses, air guns, floors, gloves, drains and a bread-feeding machine (Ref. 219).

Some of the available data and information about the potential presence of the environmental pathogen *L. monocytogenes* comes from studies conducted to detect the presence of *Listeria* spp. in lieu of *L. monocytogenes. Listeria* spp. are ''indicators'' of the potential presence of *L. monocytogenes.* (See section I.E of this Appendix for a discussion of indicator organisms). A study conducted over a 4-year time period on the prevalence of *L. monocytogenes* on produce and in the plant environment in a large produce processing plant in Poland demonstrated that the indicator organism *Listeria* spp., and the environmental pathogen *L. monocytogenes,* could be isolated from conveyor belts after blanching and from freezing tunnels (Ref. 220). Studies in a vegetable processing plant in Spain found the indicator organism *L. innocua* (commonly found when the species of *Listeria* spp. are determined) in frozen RTE vegetables and in the plant environment, e.g., washing tunnels, conveyor belts and floors (Ref. 221). *L. innocua* was more prevalent than *L. monocytogenes* in the frozen RTE vegetables and in the plant environment. In both of these examples, the presence of an ''indicator organism'' (either *Listeria* spp. or *L. innocua)* demonstrated that insanitary conditions existed that were conducive to the presence and harborage of *L. monocytogenes.*

E. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen To Contaminate Food

1. Purpose of Environmental Monitoring

Appropriate sanitation controls can minimize the presence of environmental pathogens in the plant and the transfer of environmental pathogens to food-contact surfaces and to food (Ref. 199). The purpose of monitoring for environmental pathogens in facilities where food is manufactured, processed, packed or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing (particularly strains that may have become established in the facility as resident strains) so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). Pritchard et al. noted that daily cleaning and sanitizing appeared to be effective in eliminating transient contaminants from equipment and concluded that greater emphasis needs to be placed on cleaning and sanitizing the plant environment (Ref. 216). A robust environmental monitoring program for environmental pathogens can detect these strains and enables the facility to eliminate them from the environment which can prevent contamination of food with these pathogens and, thus, prevent foodborne illnesses (Ref. 52) (Ref. 144) (Ref. 185) (Ref. 186) (Ref. 184). In the situations described in sections I.D.5 and I.D.6 of this Appendix, such a program for the environmental pathogens *Salmonella* spp. and *L. monocytogenes* might have allowed the facility to detect a problem before product contamination occurred, thereby preventing an outbreak, recall, or both, or minimizing the amount of product affected by a recall. Studies of environmental pathogens have clearly demonstrated that environmental monitoring can identify the presence of situations that can lead to contamination of food and allow actions to be taken to prevent such contamination (Ref. 216) (Ref. 187).

2. Indicator Organisms

The term ''indicator organism'' can have different meanings, depending on the purpose of using an indicator organism. As discussed in the scientific literature, the term ''indicator organism'' means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 222). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. 223). FDA considers the NACMCF definition of an indicator organism to be an appropriate working definition for the purpose of this document.

The use of ''indicator organisms'' as a verification of hygiene measures in facilities is common practice (Ref. 224). For example, it is common practice to use the presence of generic (nonpathogenic) *E. coli* in a food processing plant as an indication of whether food was prepared, packed, or held under insanitary conditions, without considering whether the insanitary conditions reflect a specific pathogen, such as *E. coli* O157:H7 or *Salmonella* spp. However, such use of an indicator organism is distinct from the use of indicator organisms as discussed in the remainder of this document—i.e., for the specific purpose of monitoring for the presence of environmental pathogens.

Environmental monitoring for environmental pathogens can be conducted by testing for the specific pathogenic microorganism (e.g., *Salmonella* spp.) or by testing for an ''indicator organism.'' The presence of an indicator organism indicates conditions in which the environmental pathogen may be present. An organism is useful as an indicator organism if there is sufficient association of conditions that could result in the presence of the indicator organism and conditions that could result in the pathogen such that there can be confidence that the pathogen would not be present if the indicator is not present. Attributes that provide scientific support for use of an indicator organism in lieu of a specific pathogen include:

- Similar survival and growth characteristics;
- A shared common source for both organisms; and
- A direct relationship between the state or condition that contributes to the presence of pathogen and the indicator organism (Ref. 223).

The presence of an indicator organism in the plant environment, including on a food-contact surface, does not necessarily mean that an environmental pathogen is in the plant or in a food produced using that food-contact surface—the indicator may be present but the pathogen may be absent. Pritchard et al., in their study on the presence of *Listeria* in dairy plant environments, concluded that, because the level of contamination was higher in environmental samples than in equipment samples, environmental contamination with *Listeria* does not

necessarily translate into contamination of equipment in the plant (Ref. 216).

Typically, a facility that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the indicator organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 144). In general, whether a facility takes subsequent steps to determine an indicator organism detected on a food-contact surface is actually the environmental pathogen depends, in part, on the risk of foodborne illness if the food being produced on a food-contact surface that has tested positive for an indicator organism were to be contaminated. For example, the risk of listeriosis is greater if the food supports growth of *L. monocytogenes.* In some cases, a facility simply assumes that a food produced using a food-contact surface that is contaminated with an indicator organism is contaminated with the environmental pathogen and takes corrective action to either reprocess it or divert it to a use that would not present a food safety concern.

3. Environmental Monitoring for *L. monocytogenes* and the Use of an Indicator Organism

Tests for the indicator organism *Listeria* spp. detect multiple species of *Listeria,* including the pathogen *L. monocytogenes.* There is Federal precedent for the use of *Listeria* spp. as an appropriate indicator organism for *L. monocytogenes.* FSIS has established regulations requiring FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure (e.g., cooking) to prevent product adulteration by *L. monocytogenes.*

FSIS has issued guidelines (FSIS Compliance Guideline for Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products) (hereinafter the FSIS *Listeria* Compliance Guideline) to help FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure comply with the requirements of 9 CFR part 430 (Ref. 225). Under the FSIS *Listeria* Compliance Guideline, FSIS-regulated establishments may establish an environmental monitoring program for *Listeria* spp. rather than for the pathogen, *L. monocytogenes.*

In general, under the FSIS *Listeria* Compliance Guideline, an FSIS-regulated establishment that receives a positive test result for an indicator organism on a food-contact surface:

- Takes corrective action (i.e., intensify the cleaning and sanitizing of the affected food-contact surface);
- Retests the affected food-contact surface; and
- Takes additional corrective action (intensified each time the test is positive for the indicator organism) and conducts additional testing until the affected food-contact surface is negative for the indicator organism.

Some segments of the food industry subject to regulation by FDA have adopted the principles, described in the FSIS *Listeria* Compliance Guideline, for corrective actions after a finding of *Listeria* spp. on food-contact surfaces in the plant. For example, in response to a request for comments on a draft guidance document directed to control of *L. monocytogenes* in refrigerated or frozen ready-to-eat foods, we received letters describing programs similar to the program in the FSIS *Listeria* Compliance Guideline, using *Listeria* spp. as an indicator organism during environmental monitoring for *L. monocytogenes* (Ref. 226) (Ref. 227) (Ref. 228) (Ref. 229). In addition, as discussed in section II.A.1 of the preamble of this document, a key finding of the CGMP Working Group Report was the importance of updating CGMP requirements to require a written environmental pathogen control program for food processors that produce RTE foods that support the growth of *L. monocytogenes.* Written comments from the food industry supported such a control program (Ref. 230). Thus, the importance of controlling *L. monocytogenes* in the environment of RTE food production facilities and using environmental monitoring to detect the presence of *L. monocytogenes* or *Listeria* spp. (as an indicator organism for *L. monocytogenes*) has been well-established.

FDA's current thinking is that *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes,* and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for *Listeria* spp., have public health benefits.

4. Environmental Monitoring for *Salmonella* spp. and the Use of an Indicator Organism

Salmonella spp. is a member of the family Enterobacteriaceae, and thus there is some relationship between the presence of *Salmonella* spp. and the presence of Enterobacteriaceae. There are few studies that have investigated the use of organisms such as Enterobacteriaceae or other members of the family Enterobacteriaceae, such as *E. coli,* to serve as an indicator organism for *Salmonella* spp. in the environment. The European Food Safety Agency (EFSA) evaluated whether environmental monitoring for Enterobacteriaceae as an indicator organism for *Salmonella* spp. (or for *Cronobacter* spp.) could be useful. Although EFSA's focus was on the utility of Enterobacteriaceae as an indicator organism in the production of a single product—i.e., powdered infant formula—their analysis may be relevant to the utility of Enterobacteriaceae as an indicator organism in other dried foods. EFSA concluded that, although there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and *Salmonella* spp. in powdered infant formula because *Salmonella* spp. is so rarely present, monitoring for Enterobacteriaceae in the product environment can be used to confirm the application of GMPs (Ref. 231). ICMSF also considered the utility of environmental monitoring for Enterobacteriaceae as an indicator organism for *Salmonella* spp. ICMSF indicates that, for powdered infant formula manufacturing, low levels of Enterobacteriaceae do not guarantee the absence of *Salmonella* spp. (Ref. 232) and recommends testing directly for the pathogen, as well as for Enterobacteriaceae. FDA agrees with EFSA and ICMSF that there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and *Salmonella* spp. during the production of powdered infant formula; FDA is not aware of any information supporting the use of an indicator organism for the purpose of environmental monitoring for *Salmonella* spp. during the production of other foods, particularly dried foods.

ICMSF recommends testing for *Salmonella* spp. in the environment for a number of other products, e.g., baked dough products (Ref. 233), dry spices receiving a kill step (Ref. 234), dried cereal products (Ref. 235), nuts (Ref. 236), cocoa powder, chocolate and confectionary (Ref. 237), and dried dairy products (Ref. 238). For most of these products ICMSF also recommends testing the environment for Enterobacteriaceae as a hygiene indicator, but not in lieu of the environmental pathogen *Salmonella* spp. Likewise, food industry guidance for low-moisture foods recommends testing for *Salmonella* spp. in the environment (Ref. 184). FDA's current thinking is that there is no currently available indicator organism for *Salmonella* spp. We request data, information, and other comment bearing on whether there is a currently available indicator organism for *Salmonella* spp. that could be used for environmental monitoring.

5. Environmental Monitoring Procedures

The procedures associated with an environmental monitoring program generally include the collection of environmental samples at locations within the facility and testing the samples for the presence of an environmental pathogen or indicator organism. One approach to defining sampling locations is to divide the facility into zones based on the risk with respect to contamination of product. A common industry practice is to use four zones (Ref. 199) (Ref. 184):

- Zone 1 consists of food-contact surfaces;
- Zone 2 consists of nonfood-contact surfaces in close proximity to food and food-contact surfaces;
- Zone 3 consists of more remote non-food-contact surfaces that are in the process area and could lead to contamination of zones 1 and 2; and
- Zone 4 consists of non-food-contact surfaces, outside of the processing area, from which environmental pathogens can be introduced into the processing environment.

Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater risk of food contamination if the environmental pathogen is detected in these zones. Information on appropriate locations for sampling within

these zones can be found in the literature (Ref. 197) (Ref. 144) (Ref. 215) (Ref. 216) (Ref. 184). Facilities should become familiar with locations in which environmental pathogens have been found in other facilities and use this information in selecting sites to sample.

Examples of appropriate food-contact surfaces that could be monitored include hoppers, bins, conveyors, tables, slicers, blenders, knives and scrapers. Testing food-contact surfaces for *Listeria* spp. is a commonly recommended verification measure for facilities producing refrigerated RTE foods (Ref. 52) (Ref. 199) (Ref. 144). Although some literature suggests that routine environmental monitoring for *Salmonella* spp. in low-moisture food environments would not normally target food-contact surfaces (Ref. 184), the data (discussed in the preamble of this document) available from investigations of food facilities following outbreaks, recalls, or reports to the RFR warrant including food-contact surfaces in a routine environmental testing program for *Salmonella* spp. However, a routine environmental monitoring program for *Salmonella* spp. may not contain the same level of food-contact surface testing (including the frequency of testing and number of samples collected) as a routine environmental monitoring program for *Listeria,* because the same benefits may not be achieved. For example:

- *L. monocytogenes* is usually the environmental pathogen of concern for most wet RTE food production environments. It is important to sample areas where the organisms are likely to be present in relatively high numbers. *L. monocytogenes* frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. *L. monocytogenes* organisms work their way out of the harborage site during production and contaminate food.
- *Salmonella* spp. is usually the environmental pathogen of concern for most dry (e.g., low-moisture) RTE food environments. Equipment used in the production of dry products is rarely wet and, thus, there is no moisture to allow growth of *Salmonella spp.* As a result, *Salmonella* harborage sites are less likely to be found on equipment and are more likely to be found in the environment in locations where food particles lodge and escape a dry cleaning process. When these locations get wet, the *Salmonella* spp. grows and contaminates other areas of the facility, eventually contaminating food-contact surfaces and food. Nevertheless, sampling food-contact surfaces (e.g., filler hoppers, conveyors, valves, sifter cuffs) can be useful, as can sampling residues such as sifter tailings and product scrapings.

Examples of appropriate non-food-contact surfaces that could be monitored include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, motor housings and vacuum canisters. Standing water in production areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for *L. monocytogenes* or *Listeria* spp. is a commonly recommended verification measure for facilities producing refrigerated or frozen RTE foods (Ref. 52) (Ref. 199) (Ref. 144) and can detect *L. monocytogenes* that is brought into the plant by people or objects. Corrective actions can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination. Recommendations for routine environmental monitoring for *Salmonella spp.* in low moisture food environments generally target non-food-contact surfaces because equipment used in the production of low-moisture foods where *Salmonella* spp. is the environmental pathogen of concern does not have the moisture to allow *Salmonella* spp. to grow and, thus, sampling non-food-contact surfaces for *Salmonella* spp. may be more effective in finding the organism than sampling food-contact surfaces. Scrapings or residues that accumulate under or above equipment are more useful samples than sponges or swabs of food-contact surfaces (Ref. 237).

As discussed in section I.E.2 of this Appendix with respect to indicator organisms, a facility that finds an indicator organism or an environmental pathogen during environmental monitoring typically conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 144).

The adequacy of a corrective action in response to environmental monitoring depends in part on the following factors related to the risk presented in a particular situation:

- Whether the environmental contamination is on a food-contact surface or a non-food-contact surface;
- The proximity of a contaminated non-food-contact surface to one or more food-contact surfaces;
- Whether there have been previous positives on the specific food-contact surface or non- food-contact surface or in the same area; and
- The environmental monitoring strategy for the type of food, and whether the food supports growth of the environmental pathogen (see the discussion of the relevance of whether a food supports the growth of an environmental pathogen in section I.D.4 of this Appendix).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, corrective actions are taken to eliminate the organism, including finding a harborage site if one exists (Ref. 144) (Ref. 185) (Ref. 184). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Corrective actions are taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Sampling and microbial testing from surfaces surrounding the area where the test organism was found are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. 144). Examples of additional corrective actions that could be taken include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (e.g., hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. 144) (Ref. 184). The types of corrective actions would depend on the type of food, the facility and the environmental pathogen.

The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. 185). However, finding the test organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Ref. 184).

The types of facilities that may conduct environmental monitoring and that could implement corrective actions on finding the test organism in the facility are quite diverse, and include facilities producing low-moisture products such as cereals, chocolate and dried milk powders and facilities producing a variety of RTE refrigerated products such as deli salads, cheeses and bagged salads. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures would depend on the facility and the equipment.

Corrective actions may involve investigative procedures when the initial corrective actions have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or product from the processing line at multiple times

during the day while the equipment is operating and producing product (Ref. 144). Another example of an investigative procedure is conducting molecular strain typing such as pulsed-field gel electrophoresis (PFGE), ribotyping, or polymerase chain reaction (PCR) analysis to determine if particular strains are persistent in the environment (Ref. 200) (Ref. 239) (Ref. 219) (Ref. 217) (Ref. 218) (Ref. 240). Molecular strain typing can indicate that strains isolated at different points in time have the same molecular ''fingerprint,'' suggesting a common source, and perhaps a harborage site, that has not been detected based on the results of routine environmental monitoring (Ref. 217) (Ref. 218). Molecular strain typing can also be used when trying to determine if a specific ingredient is the source of contamination (Ref. 239).

If environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the facility may conduct finished product testing. As discussed in section I.F of this Appendix, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If a facility detects an environmental pathogen on a food-contact surface, the facility should presume that the environmental pathogen is in the food.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The potential for food to be contaminated directly from contamination in or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food-contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment. In general, finished product testing is most appropriate when an indicator organism, rather than an environmental pathogen, is detected on a food-contact surface.

The results of finished product testing can be used in combination with the results of environmental monitoring and corrective actions to help ensure that the food released into commerce is not adulterated. For example, if a facility with an aggressive environmental monitoring program detects an indicator organism on a food-contact surface, it may use information such as the following in determining whether to release product into commerce:

- The number and location of positive sample findings, including from the original sampling and from additional/follow-up testing of areas surrounding the site of the original finding;
- The root cause analysis of the source of the contamination;
- Information on the efficacy of the facility's corrective actions (including the results of additional follow-up sampling);
- Information obtained from any finished product testing, taking into consideration the statistical confidence associated with the results.

F. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

Although FDA is not including a provision for finished product testing in this proposed rule, here we set out some considerations regarding the appropriate use of such testing. The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the food being produced or in a similar food. If the hazard were to be present in the food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing. For example, *Salmonella* spp. is a hazard that if consumed could cause serious illness, particularly in children and the elderly. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity but that is within the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify *Salmonella* spp. control than to verify control of pesticides.

Another consideration in determining whether finished product testing is appropriate is the intended consumer of the food. The greater the sensitivity of the intended consumer (as would be the case, for example, for a medical food provided to hospitalized adults), the greater the likelihood that finished product testing would be used as a verification activity.

Another consideration in determining whether finished product testing is appropriate is the impact of the food on the contaminant. For example, depending on the food, pathogens may survive in food, increase in number, or die off. Finished product testing generally is not conducted if pathogens that may be in a food would die off in a relatively short period of time (e.g., before the food reaches the consumer). For example, many salad dressings have antimicrobial properties, including low pH, high acidity, and preservatives, that are lethal for pathogens such as *Salmonella* spp. or *E. coli* O157:H7. If a facility has validated the lethality of the formulation of the salad dressing, the facility is unlikely to conduct finished product testing for pathogens such as *Salmonella* spp. or *E. coli* O157:H7, as this would not be an effective use of resources, particularly if proper formulation of the food is verified during production. In contrast, verification testing is more likely in food where pathogens can survive in a food, particularly where pathogens may grow in a food.

Another consideration in determining whether finished product testing is appropriate is the intended use of the food. For example, consumers cook many foods, e.g., dried pasta, cake mixes, and most frozen vegetables, thereby reducing pathogens. A facility should not rely on the consumer to eliminate hazards that can be prevented. However, there is little benefit in testing a food that is normally consumed following a step that can be relied on to inactivate the hazard. It is important to validate that the instructions provided to the consumer adequately reduce the pathogen of concern. It is also important to understand the customary use of the food, which may include uses that do not include the hazard reduction step. For example, dried soup mixes may be mixed with sour cream to make a dip, without the pathogen inactivation step that occurs when boiling the soup mix with water. If *Salmonella* spp. may be present in an ingredient for the soup mix, e.g., dried parsley or black pepper, and neither the supplier nor the facility treats the ingredient or the soup mix in a way that significantly reduces *Salmonella* spp., then finished product testing for *Salmonella* spp. would be warranted. Likewise, frozen peas and corn may be added to fresh salads, deli-type salads, or salsas without a pathogen inactivation step; finished product testing for *L. monocytogenes* could be warranted for these foods where this is a likely use.

Another consideration in determining whether finished product testing is appropriate is the type of controls the supplier has implemented to minimize the potential for the hazard to be present, e.g., whether the supplier uses a kill step for a pathogen or has other programs in place that will adequately reduce the hazard. A facility generally is more likely to conduct finished product testing when the supplier does not have a program that can ensure the hazard has been adequately reduced in the ingredient supplied. Another consideration is the verification procedures that are in place at the supplier and at the receiving facility. If the supplier has a well-executed control program, including a supplier approval and verification program that has been verified through audits to adequately reduce the hazard, the receiving facility performs periodic verification testing of the ingredient provided by the supplier, and the supplier has a good compliance history, the frequency of finished product verification testing by the receiving facility is low, particularly if the receiving facility has a process that further reduces the hazard. However, if the ingredient is associated with a hazard and the processes used by the supplier and the receiving facility will not significantly minimize it, or if a facility is using a new supplier, the frequency of finished product verification testing increases.

One of the most important considerations in determining whether finished product

testing is appropriate is the effect of processing on the hazard. The frequency of finished product testing generally is low when a manufacturing process significantly minimize the hazard (e.g., a 5-log reduction of a pathogen) and procedures are in place to prevent recontamination after that process; the frequency of finished product testing increases when a manufacturing process does not significantly minimize the hazard (e.g., 1- or 2-log reduction of a pathogen). For example, testing is not common for bagged spinach that is irradiated to provide a 5-log reduction of *Salmonella* spp. and *E. coli* O157:H7; finished product verification testing would be more common if the only pathogen reduction step is washing the spinach leaves in chlorinated water. Likewise, FDA noted in the preamble to the juice HACCP regulation that it was not requiring end product verification testing for juice treated to achieve a 5-log reduction in a target pathogen because the post-treatment level of microorganisms would be too low to be detected using reasonable sampling and analytical methods (68 FR 6138 at 6174).

Another important consideration in determining whether finished product testing is appropriate is whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard, either through exposure to the environment or by the addition of an ingredient after a treatment to significantly minimize a hazard. For example, verification testing is not common if a lethal treatment for a pathogen is given to food in its final package (such as a marinara sauce heated in the jar or hot-filled into the jar) but would be more common if food exposed to the environment, such as a cold gazpacho filled into a container. Likewise, verification testing generally is more frequent for foods given significant handling before packaging, regardless of whether they have previously received a treatment that would significantly minimize a hazard, if they will be consumed without a treatment lethal for pathogens that can be introduced during handling (e.g., *L. monocytogenes* or *Salmonella* spp. from the environment; pathogens such as *Staphylococcus aureus* or *Salmonella spp.* from food handlers*).* Verification testing also would be more frequent if an ingredient that has potential to be contaminated with a pathogen is added to a food that was previously treated to significantly minimize a hazard (e.g., adding seasonings to chips or crackers after frying or baking) than if all ingredients are added before the treatment.

In assessing whether to conduct verification testing and determine the frequency of that testing, a facility generally considers the impact of all the preventive control measures applied in producing the food, because multiple control measures provide greater assurance that a hazard is being controlled. For example, the frequency or finished product verification testing generally could be lower for a food that is subject to supplier controls that include audits and certificates of analysis (COAs); that contains ingredients that have been subjected to ingredient testing; that is produced under well-implemented sanitation controls that are verified through a robust environmental monitoring program; and that is treated using a validated process that significantly minimizes the hazard than for a food that is not subject to all these controls. Finished product testing generally is more frequent during initial production cycles until there is an accumulation of historical data (e.g., finished product test results that are negative for the hazard) to confirm the adequacy of preventive controls. Once this history has been established, the frequency of testing generally is reduced to that needed to provide ongoing assurance that the preventive controls continue to be effective and to signal a possible loss of control, as discussed further immediately below.

There are well-known shortcomings of product testing, especially microbiological testing, for process control purposes, and it is generally recognized that testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. 222) (Ref. 241)). Moreover, the number of samples used for routine testing often is statistically inadequate to provide confidence in the safety of an individual lot in the absence of additional information about adherence to validated control measures. This is illustrated below for *Salmonella* spp.

FDA's Investigations Operations Manual (IOM) (Ref. 242) and Bacteriological Analytical Manual, BAM, (Ref. 243) provide sampling plans to determine the presence of *Salmonella* in processed foods intended for human consumption. The stringency of the sampling plan is based on the category of the food. Category III foods are those that would normally be subject to a process lethal to *Salmonella* spp. between the time of sampling and consumption (e.g., macaroni and noodle products, frozen and dried vegetables, frozen dinners, food chemicals). Category II foods are those that would not normally be subject to a process lethal to *Salmonella* spp. between the time of sampling and consumption (e.g., fluid milk products, cheeses, nut products, spices, chocolate, prepared salads, ready-to-eat sandwiches). Category I foods are Category II foods intended for consumption by the aged, the infirm, and infants (e.g., foods produced for a hospital). FDA takes 15 samples for Category III foods, 30 for Category II foods, and 60 for Category I foods and tests a 25 g subsample (analytical unit) from each sample. To reduce the analytical workload, the analytical units may be composited (Ref. 244), with the maximum size of a composite unit being 375 g (15 analytical units). This composite is tested in its entirety for *Salmonella* spp. The probability of detecting *Salmonella* spp. for various contamination rates under the three IOM Salmonella sampling plans is shown in Table 1. (Probability of Detecting *Salmonella*.)

TABLE 1—PROBABILITY OF DETECTING SALMONELLA SPP. IN LOTS AT VARIOUS CONTAMINATION RATES UNDER THE THREE DIFFERENT IOM SALMONELLA SAMPLING PLANS (LEFT) AND THE EXPECTED NUMBER OF POSITIVE COMPOSITE SAMPLES USING WEEKLY TESTING FOR 1 YEAR UNDER THE IOM SALMONELLA SAMPLING PLANS (RIGHT)

Contamination rate	CFU/g or CFU/kg	Probability of detecting *Salmonella* spp. in a lot (percent)			Expected # of positive composites per year (weekly testing)		
		N=15*	n=30*	n=60*	n=15*	n=30*	n=60*
1 in 10	1/250g	79	96	>99	40	81	162
1 in 30	1/750g	40	64	87	20	41	82
1 in 100	1/2.5kg	14	26	45	7	15	29
1 in 300	1/7.5kg	4.9	10	18	2.5	5	10
1 in 1000	1/25kg	1.5	3	5.8	0.8	1.5	3
1 in 3000	1/75kg	0.5	1	2	0.3	0.5	1

* In the table, "n" is the number of subsamples (which are composited in groups of 15 for analysis).

The probability of detecting *Salmonella* spp. increases as the defect rate increases. For example, when 15 samples are tested, the probability of detecting *Salmonella* spp. is 14 percent when the contamination rate is 1 in 100, but 79 percent when the contamination rate is 1 in 10. For a given contamination rate, the probability of detecting *Salmonella* spp. increases with the number of samples tested. For example, at a contamination rate of 1 in 30, the probability of detecting *Salmonella* spp. increases from 40 percent if 15 samples are tested to 87 percent if 60 samples are tested.

Table 1 shows that it is clearly not feasible to attempt to identify low levels of contamination in an individual lot based on the IOM *Salmonella* sampling plan. If the contamination levels are high and 1 in 10 products are contaminated, then *Salmonella* spp. would be detected in the lot greater than 99 percent, 96 percent, and 79 percent of the time using Category I, II, and III testing, respectively. If the frequency of

contaminated units is reduced to 1 in 300, then the contaminated lot would only be detected 18 percent, 10 percent, and 4.9 percent of the time using Category I, II, and III testing, respectively. At a very low frequency of contamination (e.g., 1 in 1000) even with testing 60 samples the contaminated lot would be detected only about 6 percent of the time.

Periodic testing for trend analysis and statistical process control, however, does provide information to assess whether processes (or the food safety system) are under control over time. Data collected from multiple lots of product produced over days, months or years are used to establish a baseline for the level of control that can be attained under a functioning food safety system and to verify the system is in control or to indicate loss of control. In addition to showing the probability of detecting contamination in a lot of product for a given contamination rate, Table 1 also shows the value of periodic testing when contamination levels are low. Even though a product with 1 in 300 contaminated units is unlikely to be rejected when sampling a single lot at the Category III sampling schedule (i.e., 4.9 percent of the time), testing of finished products with this level of contamination on a weekly basis would be expected to find 2.5 positive composite samples per year. Similarly, if the background contamination rate is thought to be near 1 in 1000 but periodic testing using the Category III schedule has found 3 positives in the last year, then it seems clear that the actual frequency of contaminated units is closer to 1 in 300. Periodic testing according to the Category I *Salmonella* plan has the potential to detect situations where the contamination rates are as low as 1 in 1000. If 60 samples of a food are collected weekly, then 3,120 samples would be collected over the course of a year. Compositing these 3,120 samples into 375g analytical units would reduce the number of analytical tests to 208 (4 tests per week). If 30 samples are collected weekly, and composited, there would be 104 tests annually, or two each week. At the 1 in 1000 contamination rate there would be a greater than 95 percent confidence in seeing one or more positive tests during the year for testing composites from either 60 or 30 samples weekly. At higher rates of contamination, more positives would be detected.

There can be significant benefits to a facility testing finished products over time for process control. First, if a lot of product tests positive for a hazard, that lot of product can be disposed of such that the consumer is not exposed to the hazard (i.e., the product can be destroyed, reprocessed, or diverted to another use, as appropriate). If the testing involves enumeration of an indicator organism, it may even be possible to detect a trend toward loss of control before exceeding the criterion that separates acceptable from unacceptable. The process can be adjusted before there is a need to dispose of product. Second, the detection of loss of control, or potential loss of control, e.g., an unusual number of positives in a given period of time, allows a facility to evaluate and modify its processes, procedures, and food safety plan as appropriate to prevent loss of control in the future. In fact, the nature of the trends can provide information useful in determining the root cause of the problem (Ref. 222). A third benefit to ongoing verification testing is the accumulation of data that can help bracket any problem that occurs. For products in which there are large production runs without intervening sanitation cycles, this may provide data that can be used in conjunction with other information to limit the scope of a recall. A fourth benefit may be in detection of a problem associated with an ingredient supplier that results in changes to a supplier's processes, procedures, or food safety plan. For example, a positive in finished product due to routine verification testing was responsible for determining that hydrolyzed vegetable protein was contaminated with *Salmonella* spp., resulting in over 177 products being recalled (Ref. 24) and a recognition of the need for enhanced preventive controls for the production of this ingredient (Ref. 23). Industry commonly uses finished product testing to verify preventive controls used by the facility and by the facility's suppliers. Additionally, it is common for customers to require suppliers to conduct testing of products and ingredients being provided.

G. Metrics for Microbiological Risk Management

Recently there has been much attention paid to microbiological risk management metrics for verifying that food safety systems achieve a specified level of public health control, e.g., the Appropriate Level of Protection (ALOP), for microbial hazards. Microbiological risk management metrics are fully discussed in Annex II of the Codex ''Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)'' (Ref. 245). These metrics include traditional metrics such as microbiological criteria, process criteria, and product criteria and emerging metrics such as food safety objectives (FSO), performance objectives and performance criteria. Of particular relevance are performance objectives and performance criteria. A performance objective is the maximum frequency and/or concentration of a microbiological hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (Ref. 119). A performance criterion is the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective or an FSO (Ref. 119). FDA established a performance criterion (or performance standard) when we required that processors of juice products apply a control measure that will consistently produce, at a minimum, a 5-log reduction for the most resistant microorganism of public health significance (§ 120.24). Section 104 of FSMA (Performance Standards) requires the Secretary to determine the most significant foodborne contaminants and issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations for products or product classes. The proposed rule that is the subject of this document would not establish criteria or metrics for verifying that preventive controls in food safety plans achieve a specified level of public health control in this proposed rule. However, FDA will give consideration to appropriate microbiological risk management metrics in the future.

II. The Role of Supplier Approval and Verification Programs in a Food Safety System

A food can become contaminated through the use of contaminated raw materials or ingredients. In the past several years, thousands of food products have been recalled as a result of contamination of raw materials or ingredients with pathogens such as *Salmonella* spp. and *E. coli* O157:H7. The ingredients included peanut-derived ingredients (Ref. 19) (Ref. 20), pistachio-derived ingredients (Ref. 152), instant nonfat dried milk, whey protein, fruit stabilizers (Ref. 21) Ref. 22) (Ref. 155) and hydrolyzed vegetable protein (Ref. 153).

The incident involving *Salmonella* spp. in hydrolyzed vegetable protein illustrates the impact one supplier can have on the food industry (Ref. 60). A receiving facility (manufacturer) detected *Salmonella* spp. in verification testing of finished product. In determining the source of the contamination, the manufacturer detected *Salmonella* spp. in samples of a hydrolyzed vegetable protein ingredient and reported the finding through FDA's RFR. After FDA determined that the ingredient was a reportable food, FDA requested that the supplier notify the immediate subsequent recipients of the reported hydrolyzed vegetable protein ingredient. Over one thousand reportable food reports were submitted to FDA from numerous companies concerning the potentially contaminated hydrolyzed vegetable protein or products made with the hydrolyzed vegetable protein. The hydrolyzed vegetable protein recall involved at least eleven different commodity categories and 177 products, showing the magnitude of this contamination event originating from one supplier (Ref. 60).

FDA recently reviewed CGMP-related food recall information from 2008–2009 to assess potential root causes for the contamination events. We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls (Ref. 59). The recent large recalls of foods containing contaminated or potentially contaminated ingredients have focused attention on supplier approval and verification programs intended to help a manufacturer/processor prevent the introduction of a contaminated raw material or other ingredient into another product (Ref. 20) (Ref. 24) (Ref. 22). The application of preventive approaches by the entire supply chain (including ingredient vendors, brokers and other suppliers and, ultimately, the manufacturer of a food product) is recognized as essential to effective food safety management (Ref. 246).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw

materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe food and minimize the potential for contaminated food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program provides initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. 34). The American Spice Trade Association advocates that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. 247). The Grocery Manufacturers Association's (GMA's) Food Supply Chain Handbook, developed for ingredient suppliers to the food industry, recommends that all suppliers in the food chain consider approval programs for their own suppliers; such supplier approval programs consist of a collection of appropriate programs, specifications, policies, and procedures (Ref. 246). GMA recommends a number of verification activities that suppliers can take in its Food Supply Chain Handbook, including self-auditing, third-party auditing and product testing. GMA's handbook also references verification activities that a supplier's customers might take, including second-party audits (done by an employee of the customer) or third-party (independent) audits (conducted by persons who do not work for either the supplier or the customer). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing (Ref. 44). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. 44).

Supplier verification activities include auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as CGMP requirements of current part 110. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. 248). Other supplier verification activities include conducting testing or requiring supplier COAs, review of food safety plans and records, or combinations of activities such as audits and periodic testing.

An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. 248). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs.

The GFSI was established in 2000 to drive continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. 249). GFSI has developed a guidance document as a tool that fulfils the GFSI objectives of determining equivalency between food safety management systems (Ref. 249). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. 249). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. 249).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:

- The inspection of raw materials received;
- The provision of certificates of analysis;
- Third party certification of an Approved Supplier; or
- The completion of 2nd party supplier audits.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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[FR Doc. 2013–00125 Filed 1–4–13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2012–N–1258]

Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. FDA conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. Elsewhere in this issue of the **Federal Register**, FDA is using the results of the draft RA to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for hazard analysis and risk-based preventive controls.

DATES: Submit either electronic or written comments on the draft RA by February 15, 2013.

ADDRESSES: Submit electronic comments to *http://*

www.regulations.gov. Submit written comments to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

I. Background

On January 4, 2011, FSMA (Pub. L. 111–353) was signed into law. Section 103 of FSMA, Hazard analysis and risk-based preventive controls, amends the FD&C Act to create a new section 418 with the same name. Section 418 of the FD&C Act (21 U.S.C. 350g) contains requirements applicable to food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and mandates Agency rulemaking. Section 418(a) of the FD&C Act is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) of the FD&C Act specifies that the purpose of the preventive controls is to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). Section 418(b) of the FD&C Act requires that the hazard analysis identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility. Sections 418(c)–(i) of the FD&C Act contain additional requirements applicable to facilities, including requirements for preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule (the proposed preventive controls rule) to implement section 418 of the FD&C Act.

Section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of the activities that are included as part of the definition of the term ''facility'' under section 415 of the FD&C Act (Registration of food facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 (U.S.C. 350j) (Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report) of the FD&C Act for certain facilities as FDA deems appropriate. Section 415 of the FD&C Act directs FDA to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with FDA. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of food facilities) (hereinafter the section 415 registration regulations).

Section 103(c)(1)(C) of FSMA directs the Secretary of Health and Human Services (the Secretary) to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover: (1) Specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (2) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

Section 103(c)(1)(D)(i) of FSMA requires that the Secretary consider the results of the science-based risk analysis, and exempt certain facilities from the requirements in section 418 (including requirements for hazard analysis and preventive controls), and the mandatory inspection frequency in section 421, or modify the requirements in sections 418 or 421 of the FD&C Act, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk. Section 103(c)(1)(D)(ii) of FSMA provides, in relevant part, that the exemptions or modifications described in section 103(c)(1)(D)(i) shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the FD&C Act.

II. Qualitative Risk Assessment

As explained in the draft RA, we conducted the qualitative risk assessment to identify activity/food combinations that would be considered low risk (Ref. 1). We focused on activity/food combinations that we identified as being conducted on farms, but we did not consider activity/food combinations that would be solely within the farm definition (such as growing fruits and vegetables) and, thus, are not relevant to the requirements of section 103 of FSMA. We considered the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so better enabled us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on food on a farm warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act. In the remainder of this document, we use the term ''farm mixed-type facility'' to refer to an establishment that grows and harvests crops or raises animals and may conduct other activities applicable to farms and to food facilities co-located on farms.

In the draft RA, we describe the approach applied to define a low-risk activity and low-risk activity/food combinations to determine food types out of scope of the draft RA, and to evaluate hazards associated with foods within the scope of the draft RA (Ref. 1). We followed the risk assessment framework of the Codex Alimentarius Commission (Ref. 2), which involves hazard identification, hazard characterization, exposure assessment, and risk characterization. The draft RA addresses nine specific questions:

Question 1: What are the foods that would be manufactured, processed, packed, or held by a farm mixed-type facility?

Question 2: What are the activities that might be conducted by farm mixed-type facilities on those foods?

Question 3: What are the hazards reasonably likely to occur in those foods?

Question 4: For the purpose of determining whether an activity/food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death?

Question 5: For the purpose of determining whether an activity/food combination is low risk, what foods have inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

Question 6: What interventions significantly minimize or prevent a

hazard that is reasonably likely to occur in these foods and that is reasonably likely to cause serious adverse health consequences or death?

Question 7: Which of these activities are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death and what are these hazards?

Question 8: Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of these foods?

Question 9: Which activity/food combinations are low risk, i.e., what on-farm activity/food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death?

As discussed in the draft RA, a specific activity may have a different classification within the classes of manufacturing, processing, packing, and holding (with consequences for what regulations apply to the activity) based on whether the food being operated upon is a raw agricultural commodity (RAC) or a processed food and whether a RAC was grown or raised on the farm performing the activity or a farm under the same ownership (Ref. 1). In the draft RA, we first characterize the risk of activity/food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. We then add that regulatory overlay and characterize the risk of activity/food combinations in three regulatory groups shaped by the applicable regulatory factors and the resulting activity classifications:

- Regulatory Group Type 1: Low-risk packing and holding activities that might be conducted on a farm on food not grown, raised, or consumed on that farm or another farm under the same ownership;
- Regulatory Group Type 2: Low-risk manufacturing and processing activities that might be conducted on a farm on the farm's own RACs for distribution into commerce; and
- Regulatory Group Type 3: Low-risk manufacturing and processing activities that might be conducted on a farm on food other than the farm's own RACs for distribution into commerce.

We are seeking comments that can be used to improve:

- The approach used;
- The assumptions made;
- The data used; and
- The transparency of the draft RA.

Specifically we request comment on:

- The definitions of ''low-risk activity'' and ''low-risk activity/food combination'';
- The food types and activity/food combinations that we are considering outside the scope of the draft RA and those we are considering within the scope of the draft RA;
- The approach to characterizing the risk of an activity/food combination;
- The questions addressed by the draft RA; and
- The answers to those questions.

We submitted a draft RA to a group of scientific experts external to FDA for peer review and revised the draft RA, as appropriate, considering the experts' comments. A report concerning the external peer review is available for public review and can be accessed from our Web site (Ref. 3). We will consider public comments regarding the draft RA in preparing a final version of the RA.

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding the draft RA to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

The draft RA is available electronically at *http://www.regulations.gov* and at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2012. Available at: *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.*

2. Codex Alimentarius Commission, ''Codex Alimentarius Commission Procedural Manual, Twentieth Edition,'' 2011.

3. FDA, ''Peer Review Report. External Peer Review of the FDA/CFSAN Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2012. Available at: *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–124 Filed 1–4–13; 11:15 am]

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1–254 2
255–660 3
661–852 4
853–1126 7
1127–1712 8
1713–2192 9
2193–2318 10
2319–2614 11
2615–2878 14
2879–3310 15
3311–3826 16

CFR PARTS AFFECTED DURING JANUARY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
8894 2193
8922 853
8923 855
8924 1123
8925 1125

Executive Orders:
Executive Order 13635 (superseded by EO 13594) 649

Administrative Orders:
Memorandums:
Memorandum of December 21, 2012 647
Notice of December 28, 2012 661

5 CFR

532 1

7 CFR

301 1713
922 1127
925 1715
948 3
987 1130
1220 1

Proposed Rules:
800 2627
905 2908
906 1763
927 34
1222 ..... 188, 212
3560 672

8 CFR

103 536
212 536

9 CFR

71 2040
77 ..... 1718, 2040
78 2040
86 2040

10 CFR

20 663
30 663
40 663
50 663
70 663
72 663

Proposed Rules:
50 1154
52 1154
61 1155
73 2214
429 152
430 ..... 152, 675, 2340

12 CFR

Subchapter D 2319
Subchapter F 2319
Subchapter G 2319
Subchapter H 2319
Subchapter I 2319
Subchapter J 2319
Subchapter K 2319
Subchapter L 2319
615 2615
652 2879
1201 2319
1225 2319
1228 2319
1229 2319
1231 2319
1233 2319
1235 2319
1236 2319
1237 2319
1261 2319
1263 2319
1264 2319
1265 2319
1266 2319
1267 2319
1269 2319
1270 2319
1271 2319
1272 2319
1273 2319
1274 2319
1278 2319
1281 2319
1282 2319
1290 2319
1291 2319
1292 2319

14 CFR

21 1133
36 1133
39 ..... 5, 7, 9, 15, 857, 1723, 1726, 1728, 1730, 1731, 1733, 1735, 1739, 2195, 2197, 2198, 2331, 2615
71 ..... 1742, 1750, 1751, 2200, 2879
139 3311
420 1143

Proposed Rules:
25 1765
39 ..... 275, 1155, 1772, 1776, 2223, 2644, 2910, 3356, 3363, 3365
71 2646
121 2912

15 CFR

90 255
744 3317
748 3319

Proposed Rules:
922....1778

16 CFR

305....2200
Proposed Rules:
305....1779

17 CFR

9....1144
12....1144
23....17
Ch. I....858
171....1144
Proposed Rules:
Ch. I....909

18 CFR

40....804
381....2880
Proposed Rules:
2....17, 679
380....679

19 CFR

Proposed Rules:
351....3367

21 CFR

21....2892
520....22
558....22
1308....664
Proposed Rules:
1....3646
15....277
16....3504, 3646
106....3646
110....3646
112....3504
114....3646
117....3646, 3824
120....3646
123....3646
129....3646
179....3646
211....3646
868....1158
870....1158, 1162
872....2647

23 CFR

Proposed Rules:
655....2347

26 CFR

1....666, 3325
Proposed Rules:
1....218, 687, 913
54....218
301....218, 913

27 CFR

Proposed Rules:
9....3370

29 CFR

4022....2881

32 CFR

18....3325

33 CFR

117....669
165....25, 261, 263, 669, 1145, 1753, 2616, 3326
Proposed Rules:
100....1792, 2225, 2916
165....1795, 2650

34 CFR

Proposed Rules:
Ch. III....2919, 2923

36 CFR

Proposed Rules:
242....2350
1195....1166

37 CFR

201....1755

40 CFR

49....2210
50....3086
51....2210, 3086
52....882, 885, 887, 889, 894, 896, 897, 900, 1149, 1759, 1760, 2211, 2882, 3086
53....3086
58....3086
61....2333
63....2333
81....900, 1149
180....3328, 3333
Proposed Rules:
9....277
52....37, 45, 918, 921, 922, 924, 2354, 2359, 2872, 2878
61....2362
63....277, 2362
80....277
81....51, 924, 925
85....277
122....277
123....277
180....1798, 3377
412....277

42 CFR

84....2618

44 CFR

64....2622, 2624
67....27

45 CFR

5b....2892

46 CFR

Proposed Rules:
2....2148
24....2148
30....2148
70....2148
90....2148
91....2148
188....2148

47 CFR

1....1166
27....1166
69....2572
73....32, 266, 2078
95....1188
Proposed Rules:
20....1799, 2653
69....2600
73....2925, 2934
79....1823

48 CFR

1....2893
2....2893
22....2893
52....2893
Proposed Rules:
327....2229
352....2229

49 CFR

171....988, 1101
172....988, 1101
173....988, 1101
175....988, 1101
176....988, 1101
177....988
178....988, 1101
611....1992
Proposed Rules:
172....1119
173....1119
175....1119
571....2236, 2798, 2869
585....2798, 2869
611....2038
Ch. VIII....1193

50 CFR

17....344
223....2893
300....3338
622....907
648....33, 3346
660....580
679....267, 270
Proposed Rules:
17....59, 278, 2239, 2486, 2540
18....1942
100....2350
223....3381
226....2726
635....279
648....2249
660....72

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

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H.R. 4310/P.L. 112–239
National Defense Authorization Act for Fiscal Year 2013 (Jan. 2, 2013; 126 Stat. 1632)

H.R. 8/P.L. 112–240
American Taxpayer Relief Act of 2012 (Jan. 2, 2013; 126 Stat. 2313)

Last List January 4, 2013

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