DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, and 117

[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; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our 2013 proposed rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food. In that 2013 proposed rule, we proposed to amend the CGMP requirements to modernize them and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. We also proposed to revise certain definitions in our current regulation for Registration of Food Facilities to clarify the scope of an exemption from registration requirements for ''farms'' and, in so doing, to clarify which domestic and foreign facilities would be subject to the proposed requirements for hazard analysis and risk-based preventive controls for human food. We are taking this action because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions of these proposed rules. We are reopening the comment period only with respect to specific issues identified in this proposed rule.

DATES: Submit either electronic or written comments on the proposed rule by *December 15, 2014* Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by *December 15, 2014* (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments 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 Information and 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 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 Docket No. FDA–2011–N–0920 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: 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:

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Executive Summary

Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking

We previously proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food, as required by the FDA Food Safety Modernization Act (FSMA). The proposed requirements would apply to establishments that are required to register with us as a food ''facility.'' In this document we are proposing to revise several previously proposed requirements, taking into account the comments we have reviewed so far, because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions.

''Farms'' are exempt from the registration requirements and, thus, would be exempt from the proposed requirements for hazard analysis and risk-based preventive controls for human food. We are proposing to revise the definition of ''farm,'' as well as definitions for three activities (''harvesting'', ''holding'', and ''packing'') that play a key role in determining whether an establishment is within the ''farm'' definition. The effect of the revised definitions would be that a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm not under the same ownership. The revised definitions would not create any new circumstances where a farm that would not have been required to register under the previous proposal would now be required to register.

In the previous proposal, we asked for comment on when and how three provisions (i.e., product testing programs, environmental monitoring programs, and supplier programs) are an appropriate means of implementing the statutory directives of FSMA. We also requested comment on whether a facility should be required to address potential hazards that may be intentionally introduced for economic reasons. Some comments to the previous proposal assert that additional public comment is warranted before consideration is given to whether a final rule includes or does not include provisions that were discussed in the previous proposal but for which we had not included regulatory text in the previous proposal. In this document we are providing an opportunity for such public comment on potential requirements for product testing programs, environmental monitoring programs, supplier programs, and hazards that may be intentionally introduced for purposes of economic gain, taking into account the comments we have reviewed so far. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In the previous proposal, we requested comment on three options for classifying a facility as a ''very small business,'' with consequences for facilities in terms of eligibility for exemptions and the timeframe to comply with this rule. In this document we are proposing a definition for ''very small business'' (i.e., a business that has less than $1,000,000 in total annual sales of human food adjusted for inflation).

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

The revised ''farm'' definition would continue to describe a farm as an establishment devoted to the growing of crops, the raising of animals, or both. However, the revised ''farm'' definition would no longer limit packing and holding of RACs to the farm's own RACs; instead, a ''farm'' could now pack and hold RACs grown on another farm not under the same ownership. In addition, a farm could manufacture/process RACs by drying/dehydrating to create a distinct commodity (e.g., drying grapes to create raisins), and package and label the dried commodity, as long as there was no additional processing. An example of additional processing might include slicing fruit and then drying it, which would require additional manufacturing/processing prior to drying. Because drying/dehydrating RACs to create a distinct commodity creates a processed food, the packing and holding of raisins would be subject to the CGMP requirements for human food rather than to standards that we have separately proposed to apply to produce RACs. Given the nature of this processed food (i.e., dried RACs), we tentatively conclude that the requirements we separately proposed for packing and holding produce RACs would be sufficiently similar to the CGMP requirements to make it appropriate to specify in the regulatory text that compliance with the CGMP requirements may be achieved by complying with subpart B or with the applicable requirements for packing and holding produce RACs in the separate produce safety rule.

The previously proposed requirements for hazard analysis and risk-based preventive controls applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on critical control points to control hazards that are ''reasonably likely to occur.'' We are proposing to eliminate the term ''hazard reasonably likely to occur'' throughout the proposed requirements to reduce the potential for a misinterpretation that all necessary preventive controls must be established at critical control points (CCPs). The revised regulations would use a new term (''significant hazard'') in its place.

The defined term ''significant hazard'' would be linked to the facility's hazard analysis, which addresses risk (i.e., both the severity of a potential hazard and the probability that the hazard will occur). Thus, this term would reflect the risk-based nature of the requirements. In addition, the revised regulations would provide additional flexibility relative to the previous proposal by providing that a facility can take into account the nature of a preventive control in determining when and how to establish and implement appropriate preventive control management components, including monitoring, corrections or corrective actions, verification, and records. Table 6 in the document provides examples of flexibility provided by the rule, including flexibility provided for a facility to take into account the nature of the preventive control when determining the appropriate preventive control management components.

The proposed requirements for product testing would, if included in a final rule, require that a facility conduct product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control. The facility would be required to have written procedures for product testing, corrective action procedures to address the presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing, and records of product testing.

The proposed requirements for environmental monitoring would, if included in a final rule, require that a facility conduct environmental monitoring as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard. The facility would be required to have written procedures for environmental monitoring, corrective action procedures to address the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring, and records of environmental monitoring.

The proposed requirements for a potential supplier program would, if included in a final rule, require supplier controls when the facility's hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient (e.g., if a supplier roasts the nuts that a facility would use to manufacture an energy bar). A facility would not need to establish supplier controls if it controls that hazard, or if its customer controls that hazard. The supplier program would be written. With one exception, the receiving facility would have flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier's food safety records; or other appropriate verification activity). The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. In this circumstance, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter, unless the receiving facility determines and documents that that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

The proposed requirements regarding potential hazards that may be intentionally introduced for economic reasons would, if included in a final rule, require that a facility consider in its hazard analysis hazards that may be intentionally introduced for purposes of economic gain.

We seek comment on whether these potential requirements discussed above should be included in a final rule.

The previously proposed requirements provided for an exemption for certain facilities defined by FSMA as ''qualified facilities.'' As required by FSMA, the previously proposed requirements also included an administrative procedure whereby we could withdraw that exemption under certain circumstances. In this document, we are proposing a series of modifications to the proposed withdrawal provisions. These modifications include describing the steps we would take before withdrawing an exemption, including advance notification to the facility; a procedure for re-instatement of a withdrawn exemption; and an additional 60 days for a facility whose exemption is withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

Costs and Benefits

We summarize the domestic annualized costs of the proposed regulation with the revised provisions, including the potential requirements for product testing, environmental monitoring, a supplier program, and potential requirements regarding hazards that may be intentionally introduced for economic reasons, using both a discount rate of 3 percent and 7 percent, discounted over a 7 year period in the following table. The revised proposed regulation uses a very small business definition of $1,000,000 and includes potential additional requirements for facilities subject to subpart C to institute risk-based environmental monitoring, product testing and a supplier program as appropriate to the food, the facility and the nature of the preventive controls, and controls to help prevent hazards associated with economically motivated adulteration. As described in the updated Preliminary Regulatory Impact Analysis, for the final rule we anticipate making several modifications to our estimate of the cost of our proposed rule (see section XVII).

As in our original proposal, we lack sufficient information to fully estimate the proposed rule's likely benefits. Instead we attempt to estimate the total economic burden of the domestic illnesses that could potentially be prevented by this rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the rule would prevent some portion from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-regulated

food products that would fall under the scope of this proposed rule. The monetized cost of these illnesses is estimated to be nearly $2 billion. This ignores the costs to foreign firms and benefits to foreign consumers.

For the proposed rule to break even, by which we mean for the proposed rule to reduce the health burden to consumers by approximately the same amount as the compliance costs to industry, and if we include the costs to foreign firms but ignore the benefits to foreign consumers, the rule would have to reduce the annual social cost of the illnesses by approximately $471 million. We estimate that the average cost per illness is $2,063, so reducing the cost of illness by $471 million requires reducing the number of illnesses by at least 228,000 each year.

ORIGINAL AND REVISED ESTIMATED TOTAL COSTS BASED ON ADDITIONAL PROVISIONS AND REVISED FACILITY COUNT

	20 or fewer employees	20 to 99 employees	100 to 499 employees	500 or more employees	Total
Original Total Annualized Costs without additional provisions discounted at 7%	$208 million	$67 million	$43 million	$1 million	$319 million*
Original Total Annualized Costs without additional provisions discounted at 3%	$200 million	$65 million	$42 million	$1 million	$307 million*
Additional costs because of new provisions discounted at 7%	$19 million	$20 million	$10 million	$2 million	$52 million*
Additional costs because of new provisions discounted at 3%	$19 million	$20 million	$10 million	$2 million	$52 million*
Revised Total Annualized Costs discounted at 7%	$227 million	$87 million	$53 million	$3 million	$371 million*
Revised Total Annualized Costs discounted at 3%	$219 million	$85 million	$52 million	$3 million	$359 million*
Total Costs to Foreign Facilities (most likely cost) annualized at 7%	.....	.....	.....	.....	$100 million
Total Costs to Foreign Facilities (most likely cost) annualized at 3%	.....	.....	.....	.....	$100 million
Benefits	.....	.....	.....	.....	Unquantified

I. Background

A. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables us 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 encourages us to form partnerships with State, local, tribal, and territorial authorities. Table 1 identifies five proposed rules, issued to implement FSMA, that we discuss in this document.

TABLE 1—PUBLISHED PROPOSED RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed preventive controls rule	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule.	78 FR 78014, December 24, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal food rule	78 FR 64736, October 29, 2013.

B. 2013 Proposed Preventive Controls Rule

In the 2013 proposed preventive controls rule, we:

Proposed to amend our regulation for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMPs; currently established in part 110 (21 CFR part 110)) to modernize it;

Proposed to adjust and clarify what activities fall within the current exemption from the CGMP requirements for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs based on experience and changes in related areas of the law since issuance of the CGMP regulation;

Proposed to re-establish the provisions of current part 110 in new part 117 (21 CFR part 117);

Proposed to delete some non-binding provisions of current part 110 and requested 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;

Requested comment on additional proposed revisions or clarifications to our CGMP regulations, including whether to further implement opportunities for CGMP modernization, such as on how best to revise the current provisions for training;

Proposed to add, in newly established part 117, requirements for domestic and foreign facilities that are required to register under section 415 of 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;

Proposed to add a definition for the term ''mixed-type facilities,'' to add or modify definitions for certain activities (i.e., for ''harvesting,'' ''holding,'' ''manufacturing/processing,'' and ''packing'' activities), and to revise the definition of ''farm'' as a conforming revision in light of the proposed new definition of ''harvesting'' in our current regulation for Registration of Food Facilities (21 CFR part 1, subpart H; the section 415 registration regulations) to clarify the scope of the exemption from the section 415 registration requirements for ''farms;''

Proposed to revise the definitions, in our current regulation (implementing section 414 of the FD&C Act) for Establishment and Maintenance of Records for Foods (21 CFR part 1, subpart J; the section 414 recordkeeping requirements);

Requested comment on when and how product testing programs, environmental monitoring programs, and supplier approval and verification are an appropriate means of implementing the statutory framework of FSMA; and

Requested comment on whether a final rule should address potential hazards that may be intentionally introduced for economic reasons.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new part 117 as shown in Table 2:

TABLE 2—PROPOSED SUBPARTS IN NEW PART 117

Subpart	Title
A	General Provisions.
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Modified Requirements.
E	Withdrawal of an Exemption Applicable to a Qualified Facility.
F	Requirements Applying to Records That Must Be Established and Maintained.
G	Reserved.

In the 2013 proposed preventive controls rule, we provided an extensive background discussing:

The provisions of FSMA most directly applicable to the proposed requirements, particularly the statutory provisions of section 103 of FSMA (established in section 418 of the FD&C Act);

Hazard Analysis and Critical Control Points (HACCP) Systems;

Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding Food for Human Consumption;

The Role of Testing as a Verification Measure in a Food Safety System (including discussions about environmental monitoring as well as testing raw materials, ingredients, and finished product), largely in an Appendix to the 2013 proposed preventive controls rule (the Appendix)); and

The Role of Supplier Approval and Verification Programs in a Food Safety System (largely in the Appendix).

We also issued for public comment a ''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 risk assessment) (78 FR 3824, January 16, 2013). The purpose of the draft risk assessment was to provide a science-based risk analysis of those activity/food combinations that would be considered low risk, when conducted in a facility co-located on a farm. We used the tentative conclusions of the draft risk assessment 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 from the requirements for hazard analysis and risk-based preventive controls.

We also issued a document correcting several typographical and stylistic errors in the 2013 proposed preventive controls rule and a mistake in the date of a reference (78 FR 17142, March 20, 2013). In that correction document, we republished the Appendix in its entirety (78 FR 17142 at 17143 through 17155; the corrected Appendix) because all the references to the Appendix as published in the 2013 proposed preventive controls rule (78 FR 3646 at 3812 through 3824) had been numbered incorrectly.

C. Definition of ''Retail Food Establishment''

An establishment that meets the definition of ''retail food establishment'' is exempt from the requirements of the section 415 registration regulations and, thus, from FSMA's requirements for hazard analysis and risk-based preventive controls. Section 102(c) of FSMA requires that we revise the definition of ''retail food establishment'' in § 1.227 to clarify its intent. Some comments express concern that we did not address the requirements of section 102(c) of FSMA in the 2013 proposed preventive controls rule.

We are addressing the requirements of section 102(c) of FSMA in a separate rulemaking and plan to issue a proposed rule to amend the definition of ''retail food establishment'' in the section 415 registration regulations and the section 414 recordkeeping regulations in a future issue of the **Federal Register**.

II. Public Comments

A. Opportunities for Public Comment

We requested comments on the 2013 proposed preventive controls rule by May 16, 2013. We extended the comment periods for the 2013 proposed preventive controls rule, its information collection provisions, and the draft risk assessment in response to several requests that we do so (see Table 3).

Since issuing the 2013 proposed preventive controls rule, we conducted numerous outreach activities. For example, we held three public meetings to solicit oral stakeholder and public comments on the 2013 proposed preventive controls rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed preventive controls rule (see Table 3) (Ref. 1) (Ref. 2) (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6). We also traveled across the country and around the world to discuss the 2013 proposed preventive controls rule, as well as the other foundational FSMA proposed rules listed in section I.A, with persons who would be affected by them (Ref. 7) (Ref. 8) (Ref. 9).

TABLE 3—LIST OF **Federal Register** PUBLICATIONS REGARDING THE 2013 PROPOSED PREVENTIVE CONTROLS RULE

Description	Publication
2013 proposed preventive controls rule, requesting comments by May 16, 2013	78 FR 3646, January 16, 2013.
Notice of availability of the draft risk assessment, requesting comments by February 15, 2013.	78 FR 3824, January 16, 2013.
Notice of public meeting (held in Washington D.C. on February 28, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 6762, January 31, 2013.
Notice of public meetings (held in Chicago, IL on March 11, 2013 and in Portland, OR on March 27, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 10107, February 13, 2013.
Notice extending comment period, until May 16, 2013, for the information collection provisions of the 2013 proposed preventive controls rule.	78 FR 11611, February 19, 2013.
Reopening of the comment period, until May 16, 2013, for the draft risk assessment	78 FR 15894, March 13, 2013.
Notice of correction for the 2013 proposed preventive controls rule	78 FR 17142, March 20, 2013.
Notice extending the comment period, until September 16, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 24691, April 26, 2013.
Notice extending the comment period, until September 16, 2013, for the draft risk assessment.	78 FR 24693, April 26, 2013.
Notice extending the comment period, until November 15, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 48636, August 9, 2013.
Notice extending the comment period, until November 22, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 69604, November 20, 2013.

B. Overview of Public Comments on the 2013 Proposed Preventive Controls Rule

We received more than 8000 submissions on the proposed rule by the close of the comment period, each containing one or more comments. We received submissions from diverse members of the public, including food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress, Federal, State, local, and tribal Government Agencies; and other organizations. Some submissions included signatures and statements from multiple individuals.

Comments address virtually every provision of the 2013 proposed preventive controls rule, including our requests for comment on including additional provisions that we did not include in the proposed regulatory text. Although some comments focus on specific details of the proposed requirements (such as whether the rule should define the term ''allergen cross-contact'' rather than the term ''cross-contact''), other comments are broad in nature (such as comments addressing the overall framework of the proposed requirements for hazard analysis and risk-based preventive controls in proposed subpart C). Some comments question whether the proposed requirements reflected a risk-based approach (such as comments about how the requirements for hazard analysis and risk-based preventive controls would apply to facilities co-located on farms). Some comments assert that additional public comment would be warranted before any consideration of whether a final rule should or should not include provisions discussed in the proposed rule, but for which we had not included proposed regulatory text, such as potential requirements for product testing, environmental monitoring, a supplier approval and verification program, and potential hazards that may be intentionally introduced for economic reasons.

C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

In December 2013, we issued a statement noting the extensive input we have received from produce farmers and others in the agricultural sector on the 2013 proposed produce safety rule and the 2013 proposed preventive controls rule (Ref. 8). We stated that we believe that significant changes will be needed in key provisions of the two proposed rules affecting small and large farmers, such as certain provisions affecting mixed-use facilities (i.e., facilities co-located on a farm). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our new thinking. We noted that there may be other revisions to the proposed rules that we would issue for public comment, and that we would determine the scope of the revised proposals after we complete our initial review of written comments.

III. Scope of the Supplemental Notice and Our Request for Public Comment

In this document, we are proposing:

Modifications to our proposed revisions to the definitions, in the section 415 registration regulations, for ''farm,'' ''harvesting,'' holding,'' and ''packing,'' with conforming changes in the section 414 recordkeeping regulations and the proposed preventive controls rule;

Modifications to our proposed revisions to the current exemption, in the CGMP regulations, for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs;

Revisions to several definitions we proposed to apply to the requirements for hazard analysis and risk-based preventive controls, including definitions for ''environmental pathogen,'' ''hazard,'' ''reasonably foreseeable hazard,'' and ''very small business'';

New definitions for ''significant hazard,'' ''pathogen,'' and ''you'';

Revisions to the proposed procedures that would govern withdrawal of an exemption from a ''qualified facility,'' including clarifications about the steps we would take before issuing an order to withdraw the exemption, an expanded timeframe for a facility to comply with an order withdrawing an exemption, and a mechanism for a withdrawn exemption to be re-instated; and

A series of revisions to the proposed requirements for hazard analysis and risk-based preventive controls (proposed subpart C) to:

Emphasize the risk-based nature of the preventive controls and requirements for monitoring, corrective actions, and verification activities;

Reduce the potential for misinterpretation that the rule requires

that all necessary preventive controls be established at CCPs for all hazards that a facility addresses in its food safety plan;

Increase flexibility for a facility to determine, based on the nature of a preventive control, when requirements for ''preventive control management components'' (i.e., monitoring, corrective actions, and verification) are appropriate;

Substitute the pronoun ''you'' for ''the owner, operator, or agent in charge of the facility'' throughout these proposed requirements;

Substitute the term ''adequate'' (which is a term we proposed to define) in place of the term ''sufficient'' (which we did not propose to define);

Improve readability, through rearrangement of some of the proposed regulatory text and editorial revisions (such as increased use of active voice).

In this document, we also are providing an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain, including definitions of terms (i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier'') that would be used in some of those potential requirements. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In this document, we also are informing stakeholders of a supplemental notice of proposed rulemaking, published elsewhere in this issue of the **Federal Register,** to amend the 2013 proposed animal food rule. That supplemental notice includes proposed revisions that would address comments about the practice of human food manufacturers sending by-products to local farmers or animal food manufacturers for use as animal food.

We discuss these proposed requirements in sections V through XV. Because several of the proposed revisions relate to the overall framework in subpart C for hazard analysis and risk-based preventive controls, we are including the complete regulatory text for proposed subpart C. However, in this document, we are reopening the comment period only with respect to the issues specified in this section III.

Importantly, the proposed revisions to the provisions we have included in the regulatory text are based on a preliminary review of the comments. We will complete our review of comments previously submitted and consider the comments responsive to this supplemental notice of proposed rulemaking in developing the final rule.

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

In the 2013 proposed preventive controls rule, we described the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations. We focused on the framework that governs whether an establishment that grows and harvests crops or raises animals satisfies the definition of ''farm'' because the facility registration requirements of section 415 of the FD&C Act do not apply to ''farms.'' When we implemented the statutory requirements for registration of food facilities, we established a definition for ''farm'' that first describes a farm as a facility devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both (§ 1.227; 68 FR 58894, October 10, 2003). Although that definition of ''farm'' then provides that farms also pack or hold food, it limits facilities that fall within the definition of ''farm'' to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Thus, under the current framework, an establishment that is devoted to the growing and harvesting of crops, but also packs and holds food not grown or raised on that farm or on another farm under the same ownership, would fall outside the definition of ''farm'' and be required to register as a food facility. Because an establishment that is required to register as a food facility is subject to the requirements of section 418 of the FD&C Act, under the current framework a determination of whether an establishment devoted to the growing and harvesting of crops is subject to FSMA's requirements for hazard analysis and risk-based preventive controls depends, in part, on where the food that the establishment packs or holds is grown or raised.

Under the current framework, a key factor in whether an establishment falls within the definition of ''farm,'' even with respect to crops it grows and harvests itself, is whether the activities conducted by the farm fall within definitions of ''harvesting,'' ''packing'' or ''holding'' (which are within the ''farm'' definition). As discussed in the 2013 proposed preventive controls rule, section 103 of FSMA directs us to conduct rulemaking to clarify the on-farm manufacturing, processing, packing and holding activities that would trigger a requirement for an establishment that is also a farm to register as a food facility and, thus, be subject to the requirements for hazard analysis and risk-based preventive controls with regard to its non-farm activities (78 FR 3646 at 3674). In the 2013 proposed preventive controls rule, we explained 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.

In the 2013 proposed preventive controls rule, we also articulated a comprehensive set of organizing principles that formed the basis for proposed revisions to definitions that classify activities on-farm and off-farm in the section 415 registration regulations (the 2013 organizing principles; see Table 3 in the 2013 proposed preventive controls rule). Because these definitions also are established in the section 414 recordkeeping regulations, these organizing principles also would form the basis for proposed revisions to definitions that classify activities on-farm and off-farm in the section 414 recordkeeping regulations.

In the 2013 proposed preventive controls rule, we proposed to add a definition for the term ''mixed-type facilities,'' to add or modify definitions for certain activities (i.e., for ''harvesting,'' ''holding,'' ''manufacturing/processing,'' and ''packing'' activities), and to revise the definition of ''farm'' as a conforming revision in light of the proposed new definition of ''harvesting.''

In sections V and VI, we discuss comments on these and other provisions of the 2013 proposed preventive controls rule that are leading us to propose revised definitions for ''farm,'' ''harvesting,'' ''packing,'' and ''holding''; and re-classify some activities as harvesting, packing, or holding. Briefly, the proposed changes would:

Provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACS;

Include, within the ''farm'' definition, a description of packing activities that include packaging RACs grown or raised on a farm without additional manufacturing/processing;

Provide for ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC is an activity that is within the ''farm'' definition;

Provide that activities performed incidental to packing a food would be ''packing'' activities;

Provide that activities performed incidental to holding a food would be ''holding'' activities;

Provide for drying/dehydrating RACs to create a distinct commodity (such as the on-farm drying of grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing, to remain within the farm definition;

Seek comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition;

Subject the packaging, packing, and holding of dried RACs by farms and farm mixed-type facilities to the CGMP requirements in subpart B of proposed part 117 as well as provide that compliance with these CGMP requirements may be achieved by complying with the applicable requirements for packing and holding produce RACs in the separate produce safety rule; and

Reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. These changes in activity classification would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as a food facility, but would not result in any new circumstance where a farm would now be required to register as a food facility.

Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed animal food rule. That supplemental notice includes a discussion of farming models for raising animals, including contract farming, fully vertically integrated farming, and cooperative farming. That supplemental notice asks for comment on whether feed mills associated with fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition (current or proposed revision) should be required to register as a food facility under section 415 of the FD&C Act and, if so, what revisions to the farm definition would be necessary.

V. The ''Farm'' Definition

In this section of this document, we are:

Proposing modifications to our proposed revisions to the ''farm'' definition;

Proposing modifications to our proposed revisions to the definitions of ''harvesting,'' ''holding,'' and ''packing'' as conforming amendments to the revised ''farm'' definition''; and

Proposing modifications to our proposed revisions to the current exemption, in the CGMP regulations, for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs.

We are reopening the comment period with respect to these revised definitions (proposed § 117.3) and this revised exemption (proposed § 117.3(k)). See section VI for additional revisions that we are proposing to the definitions of ''holding'' and ''packing.''

A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

Consistent with the organizing principles regarding classification of activities on-farm and off-farm, we proposed to define ''harvesting,'' as a new definition in §§ 1.227 and 1.328, to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed 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 RAC into a processed food. The proposed definition included examples of activities that would be harvesting. As a conforming change to the proposed definition of ''harvesting,'' we proposed to revise the definition of ''farm'' in current §§ 1.227(b)(3) and 1.328 to delete examples of harvesting that currently appear in the ''farm'' definition.

We proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, 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 into a processed food.

We proposed to revise the definition of ''packing'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on a farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC into a processed food.

B. Conducting Packing and Holding Activities on Others' RACs

1. Comments

Some stakeholders expressed concern, in public sessions and in written comments, about how the proposed requirements for packing and holding RACs would apply to a farm that would be subject to the requirements for hazard analysis and risk-based preventive controls because the farm packs or holds produce grown on others' farms. Comments assert that classifying establishments as being within the ''farm'' definition, or outside the ''farm'' definition, based on who owns the RACs being packed is not a risk-based classification. These comments also compare the requirements that would apply to a farm when packing produce in accordance with the 2013 proposed preventive controls rule to the requirements that would apply to a farm when packing produce in accordance with the 2013 proposed produce safety rule. In general, these comments express concern about the lack of clarity and consistency in the requirements for packing and holding RACs under the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule. Some of these comments assert that treating on-farm packing and holding of RACs differently depending on whether the RACs are grown on that farm (or another farm under the same ownership) or grown on a different farm under different ownership, fails to reflect modern, cooperative farming practices and to be risk-based. Comments also assert that it unreasonable to force many farms to comply with two different sets of requirements depending on whether they are packing and holding their own produce or packing and holding produce from another farm. In essence, comments assert it would be more appropriate for farm activities such as packing and holding produce to be treated consistently under the two rules. Comments also generally assert that the requirements in the 2013 proposed produce safety rule for packing and holding activities (which would not require hazard analysis and risk-based preventive controls) are more appropriate for farms than the requirements in the 2013 proposed preventive controls rule for packing and holding activities (which would require

hazard analysis and risk-based preventive controls).

Some comments find it confusing for the definition of ''farm'' to start by describing a farm as a ''facility'' in light of the definition of ''facility'' in section 415(o)(2) of the FD&C Act as a facility required to register under section 415 of the FD&C Act.

2. Proposed Revisions to the Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

In the rulemakings to establish the section 415 registration regulations and the section 414 recordkeeping regulations, we defined ''farm'' with the goal of doing so in a manner recognizing the traditional activities of establishments commonly recognized to be farms (see the discussions at 78 FR 3646 at 3676–3677 and 3679). As already noted (see section V.A), we proposed to expand the definition of ''packing'' to include activities traditionally performed by a farm to prepare its own RACs for storage and transport and to expand the definition of ''holding'' to include activities traditionally performed by a farm for the safe or effective storage of its own RACs. Comments assert that the packing and holding of others' RACs is a traditional and common activity by farms and that the definition should not distinguish between activities performed by a farm on its own RACs and activities performed on RACs from other farms.

We tentatively conclude that it is appropriate for packing and holding of RACs, including produce, conducted on farms to remain within the farm definition. This would result in packing and holding of covered produce being subject to the proposed produce safety rule, regardless of whether the activity is conducted on the farm's own produce or whether the activity is conducted on others' produce. This also would have consequences beyond the preventive controls rule and the produce safety rule. For example, the revised ''farm'' definition would be established in both the section 415 registration regulations and in the section 414 recordkeeping regulations (see the revised regulatory text for proposed §§ 1.227 and 1.328, respectively). Under the revised ''farm'' definition in the section 414 recordkeeping regulations, an establishment that packs and holds others' RACs would no longer be required to establish and maintain records identifying the immediate previous sources of those RACs and immediate subsequent recipients of those RACs. In addition, the scope of covered establishments would change for other statutory requirements that depend, in relevant part, on whether an establishment is a facility subject to the section 415 registration regulations. For example, this would be the case for requirements for the Reportable Food Registry (under section 417 of the FD&C Act), mandatory recall (under section 423 of the FD&C Act), and regulations that we have proposed to establish regarding intentional contamination related to terrorism (under sections 418 and 420 of the FD&C Act; see the proposed intentional adulteration rule, 78 FR 78014). We tentatively conclude that impacts such as these, while not always optimal, are necessary to establish a sensible framework of risk-based regulations that both implement FSMA and reflect common farm activities. Elsewhere in this issue of the **Federal Register**, a supplemental notice of proposed rulemaking regarding the produce safety rule (the produce safety supplemental notice) discusses impacts such as these, including a request for comment on whether to include in the final produce safety rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment. The produce safety supplemental notice also requests comment on whether it would be appropriate to also require the farm that receives the shipment maintain such record of information and, if so, for what specified period of time.

Therefore, taking into account the comments we have reviewed so far we are proposing to revise the ''farm'' definition so that it would no longer limit establishments that fall within the ''farm'' definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised ''farm'' definition, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it packs and holds RACs grown on another farm. To limit the potential for confusion related to the term ''facility,'' we are proposing to substitute the term ''establishment'' for the term ''facility'' in the revised definition of ''farm.'' As a conforming change relevant to this substitution, we are adding to the ''farm'' definition the criterion, in the definition of ''facility,'' that the establishment is ''under one ownership,'' to retain that aspect of the current ''farm'' definition in the revised definition. For additional discussion about manufacturing/processing activities that would make an establishment subject to the section 415 registration regulations, see sections V.D and VII.

We also are proposing that the packing activities (which may include packaging) that we had proposed to include in the expanded definition of ''packing'' for farms and farm mixed-type facilities be included in the ''farm'' definition rather than in an expanded definition of ''packing.'' Under the revised ''farm'' definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the ''farm'' definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing. Packaging activities would continue to be considered manufacturing/processing (78 FR 3646 at 3681–3682); however, packaging a RAC would not transform the RAC into a processed food (see the discussion in the 2013 proposed preventive controls rule about whether an activity transforms a RAC into a processed food (78 FR 3646 at 3678–3679)). Importantly, we are proposing limitations on what would be included within this addition to the ''farm'' definition. This proposed provision would not provide that packaging RACs would remain within the ''farm'' definition if the packaging includes additional manufacturing/processing (e.g., the application of ''modified atmosphere packaging''). Such additional processing activities are not akin to packing (see the discussion in the 2013 proposed preventive controls rule (78 FR 3646 at 3686) that certain packaging activities conducted on a farm are akin to packing).

We are not proposing any changes to the ''farm'' definition that we would establish in part 117, because the proposed ''farm'' definition for the purpose of part 117 simply referred to the ''farm'' definition in the section 415 registration regulations.

The revised ''farm'' definition would require conforming changes to the proposed definitions of ''harvesting,'' ''holding,'' and ''packing'' (in the section 415 registration regulations, the section 414 recordkeeping regulations, and the proposed preventive controls rule) to remove limitations that the food be grown on the same farm or a farm under the same ownership. (See the revised regulatory text for proposed §§ 1.227, 1.328, and 117.3). In addition:

The revised regulatory text for the definition of ''harvesting'' includes ''field coring'' as an additional example of a harvesting activity. See section V.C for a discussion of this proposed additional example.

The revised regulatory text for the definition of ''holding'' includes revisions that we are proposing in response to comments about how the definition of ''holding'' would apply to facilities such as grain elevators and warehouses. See section VI.A through VI.E for a discussion of those proposed revisions.

The revised regulatory text for the definition of ''packing'' includes changes that we are proposing to provide for activities performed incidental to packing a food. See section VI.F for discussions of those proposed revisions.

The revised definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing'' would, if finalized, require changes to guidance documents we issued regarding the section 415 registration regulations and the section 414 recordkeeping regulations, including specific examples of circumstances that would make an establishment subject to those requirements (e.g., Ref. 10, Ref. 11, Ref. 12, and Ref. 13). We intend to update affected guidance documents to reflect the final definitions.

C. Field Coring as a Harvesting Activity

1. Comments

Some comments ask us to specify that activities such as ''core in field'' and ''clean and core'' are considered harvesting, because these activities are no different from an example (i.e., ''trimming of outer leaves of'') included in the regulatory text of the definition of ''harvesting.''

2. Proposed Revision to the Definition of ''Harvesting''

We are proposing revisions to the definition of ''harvesting'' in addition to the revisions, discussed in section V.B.2, that would be conforming amendments in light of the revised ''farm'' definition. We are proposing to include ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity. Under the revised ''harvesting'' definition, it would be clear that an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it conducts field coring of produce. The revised definition of ''harvesting'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. In this section of this document, we are reopening the comment period with respect to including ''field coring'' as an example of a harvesting activity in this revised definition of ''harvesting'' (proposed § 117.3).

D. Drying/Dehydrating Raw Agricultural Commodities To Create a Distinct Commodity

1. Comments

Some comments refer to our discussion, in the 2013 proposed preventive controls rule, about guidance jointly developed by FDA and the U.S. Environmental Protection Agency (EPA) regarding whether or not various activities transform RACs into processed foods, including a joint conclusion 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 (78 FR 3646 at 3678–3679). In our discussion, we described a series of policy statements and guidance documents, issued by FDA and EPA regarding whether or not various activities transform RACs into processed foods (78 FR 3646 at 3678–3679). We noted that FDA and EPA have jointly concluded 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 (see, e.g., (Ref. 14). We referenced a policy statement issued by EPA on the status of dried commodities as RACs (the 1996 EPA policy statement; 61 FR 2386, January 25, 1996). We also gave two examples of when we would consider that drying a RAC created a processed food: (1) Drying grapes to create raisins; and (2) drying fresh herbs (such as peppermint) to create dried herbs, because in both these instances drying creates a distinct commodity and therefore a processed food.

The comments contrast the growing and harvesting (including drying) of ''natural condition raisins'' (produced with sun-drying or artificial dehydration) with raisins subject to additional processing and packing (e.g., sorting, cleaning or seeding) at an off-farm facility. The comments maintain that the traditional activities of raisin grape farmers associated with growing and harvesting ''natural condition raisins'' on farm are completely separate and distinct from the processing and packing of ''processed raisins'' at a raisin processing facility. They note that raisin grape farmers generally dry their grapes either by cutting the grape clusters and placing them on trays to be naturally sun dried, or by allowing the grapes to dry naturally on the vine. In both instances, there is no intervention by the farmer in the drying process; rather, the drying process occurs naturally through the action of the sun. These comments ask us to recognize this distinction and provide in the final rule that on-farm activities such as drying ''natural condition raisins'' in the field are exclusively subject to the produce safety rule and that processing facility operations are subject to the preventive controls rule. They also specifically mention the 1996 EPA policy statement and ask us to determine that it does not apply for the purposes of implementing FSMA.

2. Proposed Revisions to the ''Farm Definition'' Regarding Drying/Dehydrating RACs To Create a Distinct Commodity When the Drying/Dehydrating Is Akin to Harvesting and There Is No Additional Processing

The processes described in the comments for drying grapes to ''natural condition raisins'' are akin to other harvesting activities traditionally conducted by farms on RACs grown and harvested on farms, because they are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food (see 78 FR 3646 at 3681 and the proposed definition of harvesting in proposed § 117.3).

We continue to consider that drying a RAC to create a distinct commodity causes it to become a processed food and, thus, is a manufacturing/processing activity for the purpose of the section 415 registration regulations. However, to the extent that the comments are asking us to determine that drying a RAC to create a distinct commodity can, under circumstances such as those described in the comments, remain within the ''farm'' definition, we tentatively conclude that it is appropriate to do so, provided that the drying/dehydrating process is akin to harvesting. However, we would continue to classify drying RACs to create a distinct commodity as manufacturing/processing rather than re-classify this activity as harvesting.

We do not consider it necessary or prudent to classify this activity in two different ways for the purposes of the ''farm'' definition and determining our responsibilities for antimicrobial substances.

To provide for drying/dehydrating that is akin to harvesting to remain within the farm definition, taking into account the comments we have reviewed so far we are proposing that farms include establishments that, in addition to growing and harvesting crops, raising animals, or both, manufacture/process RACs by drying/dehydrating the RACs to create a distinct commodity, and/or packaging and/or labeling such commodities, without additional manufacturing/processing (see the revised regulatory text for the ''farm'' definition in proposed §§ 1.227 and 1.328). This revised ''farm'' definition would specifically address this circumstance because otherwise it would not be within the ''farm'' definition. Drying/dehydrating that is akin to harvesting would not trigger the requirement to register as a facility and would not trigger the requirements for hazard analysis and risk-based preventive controls. Likewise, packaging and/or labeling the dried commodities (which are processed food), would not trigger the requirement to register as a facility and would not trigger the requirements for hazard analysis and risk-based preventive controls. As a companion change, we are proposing that the ''farm'' definition explicitly provide that packing and holding the dried commodities (which are processed food) is within the ''farm'' definition. Whether a farm would be subject to the produce safety rule would depend on factors included in the produce safety rule, such as whether the RACs satisfy criteria for ''covered produce.''

Importantly, we are proposing limitations on when this special circumstance would apply. This proposed provision would not provide that drying/dehydrating fruit would remain within the ''farm'' definition if the dried/dehydrated fruit is subject to additional manufacturing/processing, such as cutting the fruit or applying sulfites (e.g., when manufacturing/processing dried apples). Such additional processing activities are not akin to harvesting. They also are not necessary for safe storage of the crop (which would be holding; see sections VI.C., VI.E, and VII.C and Table 1 in the Appendix to this document). A farm that also manufactures/processes products such as dried, cut apples would be a farm mixed-type facility, subject to the section 415 registration regulations and FSMA's requirements for hazard analysis and risk-based preventive controls for such activities.

E. One General Physical Location

1. Comments on Whether the ''Farm'' Definition Should Specify That a Farm Is in ''One General Physical Location''

Some comments emphasize that farms throughout the country are now made up of multiple, often non-contiguous fields due to geographic and topographic conditions, local development patterns, and the fact that a single ''farm'' today often derives from multiple previous farms due to the need to achieve economic efficiencies. Some comments explain that as farm land increasingly is partitioned into smaller and smaller parcels through estate divisions or for other reasons, farmers purchasing land find that they are rarely able to purchase adjacent parcels. These comments ask us to modify or remove the phrase ''in one general physical location'' in the ''farm'' definition. One suggested modification is to replace the phrase ''in one general physical location'' with an explanatory sentence, such as one clarifying that a farm may consist of one or more parcels of land (or water) and may include one or more structures (e.g., outbuildings, barns, greenhouses, etc.).

2. Request for Additional Comment on Whether the ''Farm'' Definition Should Specify That a Farm Is in ''One General Physical Location''

During the rulemaking to establish the ''farm'' definition in the section 415 registration regulations, we explained that a farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens (68 FR 5378 at 5381, February 3, 2003). However, we did not propose to include this explanatory sentence in the regulatory text. Comments addressing ''one general physical location'' focused on how specifying ''in one general physical location'' would affect whether the farm would be subject to the section 415 registration regulations. Our response to those comments focused on the nature of the activities being conducted rather than on the contiguous or non-contiguous nature of parcels of land or nets (68 FR 58894 at 58906, October 10, 2003).

The definition of ''facility'' in the section 415 registration regulations likewise specifies that a facility means ''any establishment, structure, or structures under one ownership at one general physical location . . .'' However, this definition specifically adds an explanatory statement that a facility may consist of one or more contiguous structures (§ 1.227). During the rulemaking to establish this definition of ''facility,'' we explained that we proposed to include this explanatory sentence in the regulatory text as a result of comments that we received during our early outreach efforts (68 FR 5378 at 5381, February 3, 2003).

We are seeking comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition. In responding to our request for comment on this issue, we ask commenters to carefully consider what, if any, impacts removing or modifying this phrase could have on other rules that already include (or have proposed to include) the same definition of ''farm'' as would be established in the section 415 registration regulations, as well as how such impacts would best be addressed. For example, elsewhere in this issue of the **Federal Register** the produce safety supplemental notice seeks comment on how we should interpret ''in one general physical location'' for the purposes of enforcing that rule. The produce safety supplemental notice explains that specifying that a farm is in ''one general physical location'' could impact classification of farms subject to the produce safety rule as a ''small business'' or ''very small business'' and, thus affect the compliance date for that farm.

F. Proposed Revisions to the Exemption From CGMP Requirements for ''Farms'' and Activities of ''Farm Mixed-Type Facilities'' That Fall Within the ''Farm'' Definition

1. 2013 Proposed Revisions to the Exemption From the CGMP Requirements for Establishments Engaged Solely in the Harvesting, Storage, or Distribution of One or More RACs

In the 2013 proposed preventive controls rule, we proposed to adjust and clarify what activities fall within the current exemption from the CGMP requirements for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs (''RAC exemption'') based on experience and changes in related areas of the law since issuance of the CGMP regulation. We proposed to provide that the CGMP requirements of subpart B would not apply to ''farms,'' activities of ''farm mixed-type facilities'' that fall within the ''farm'' definition, or the

holding or transportation of one or more RACs (proposed § 117.5(k)).

In the 2013 proposed produce safety rule, we proposed to implement section 419 of the FD&C Act (standards for produce safety) by establishing, in part 112, standards for the growing, harvesting, packing, and holding of produce for human consumption. The proposed standards for produce safety would apply only to RACs (see proposed § 112.1(a) and section 419(a)(1)(A) of the FD&C Act).

2. Consequential Revision to the RAC Exemption in Light of Proposed Changes to the ''Farm'' Definition

As discussed in section V.D of this document, we are proposing that an establishment that is devoted to the growing and harvesting of crops, the raising of animals, or both can remain within the farm definition if it dries/dehydrates RACs to create a distinct commodity, and/or packages and/or labels such commodities, without additional manufacturing/processing. A farm that does so would transform a RAC into a processed food. The growing and harvesting of produce RACs that would be covered by the proposed produce safety rule would be subject to the standards for produce safety, but the dried commodities that are processed food would not. Like any other processed food, such dried commodities would be subject to the CGMP requirements (proposed subpart B) and would not be eligible for a ''RAC exemption,'' whether the current RAC exemption in § 110.19 or the proposed ''RAC exemption'' in proposed § 117.5(k).

Therefore, as a consequence of our proposal to provide for drying/dehydrating that is akin to harvesting to remain within the farm definition, we also are proposing to revise the exemption from CGMP requirements for ''farms'' and activities of ''farm mixed-type facilities'' that fall within the ''farm'' definition to provide that if a ''farm'' or ''farm mixed-type facility'' dries/dehydrates RACs to create a distinct commodity, the CGMP requirements apply to the packaging, packing, and holding of the dried commodities. As discussed in section V.G of this document, we tentatively conclude that the specific steps that are necessary to ensure the safety of produce that an establishment packs and holds would be the same regardless of the specific regulatory framework applicable to the establishment. Given the nature of the processed food that would be subject to the CGMP requirements (i.e., dried RACs), we tentatively conclude that the requirements we separately proposed for packing and holding produce RACs would be sufficiently similar to the CGMP requirements to make it appropriate to specify in the regulatory text that compliance with the CGMP requirements may be achieved by complying with subpart B or with the applicable requirements for packing and holding produce RACs in the separate produce safety rule. However, we do not intend to issue a final rule on this specific option for achieving compliance with the CGMP requirements that would apply to processed food produced through drying/dehydrating RACs until we issue the final produce safety rule.

3. Comments on the Proposed RAC Exemption

Some comments ask us to exempt the harvest and immediate transport of raw fishery commodities from the CGMP requirements. Other comments ask us to exempt facilities that conduct hulling and drying operations on shell nuts from the CGMP requirements.

4. Proposed Additional Revisions to the RAC Exemption To Clarify Applicability to Certain RACs

We are proposing to clarify how the RAC exemption applies to seafood RACs by specifying that subpart B does not apply to fishing vessels that are not subject to the registration requirements of part 1, subpart H of this part in accordance with § 1.226(f). Section 1.226(f) describes fishing vessels that are exempt from the registration requirements as those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. Section 1.226(f) also specifies that fishing vessels otherwise engaged in processing fish are subject to the registration requirements, and describes ''processing'' for the purpose of determining the exemption to mean handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel. The practices identified in § 117.226(f) (heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel) that warrant an exemption from registration are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in § 110.19.

We also are proposing to clarify how this exemption applies to activities commonly conducted on nuts at a facility that is not a farm or farm-mixed type facility by specifying that subpart B does not apply to hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts). Hulling, shelling, and drying nuts (without additional manufacturing/processing), are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in § 110.19.

G. Comparing Proposed Requirements for Packing Produce Under the 2013 Proposed Preventive Controls Rule to Proposed Requirements for Packing Produce Under the 2013 Proposed Produce Safety Rule

1. Comments

Some stakeholders expressed concern, in public sessions and in written comments, about the proposed requirements that would apply to an off-farm facility that packs and holds produce. These comments focus on how the proposed requirements for an off-farm facility that packs and holds produce under the requirements of the 2013 proposed preventive controls rule would be different from the requirements, under the 2013 proposed produce safety rule, that would apply to on-farm packing and holding of produce. These comments assert that the status of an establishment as a facility subject to the section 415 registration requirements should not be used as justification to subject packing and holding activities to different standards if there is no risk-based reason to do so. Some comments assert that the standards described in the 2013 proposed produce safety rule are ''more than adequate'' for the safe handling and packing of raw, intact fresh produce, regardless of commodity, size of operation, or source of produce. These comments also assert that there is no evidence to suggest that different requirements for off-farm establishments that pack and hold produce are needed to prevent contamination.

2. Summary of the Similarities and Differences for Off-Farm Packing and Holding Compared to On-Farm Packing and Holding

The specific steps that are necessary to ensure the safety of produce that an establishment packs and holds generally would be the same regardless of whether the establishment is on-farm or off-farm. For example, several of the

CGMP requirements that would apply to an off-farm packing facility (e.g., provisions for employee health and hygiene, the plant and its grounds, sanitary operations and facilities, and equipment and utensils) have an analogous counterpart in the 2013 proposed produce safety rule. In addition, although an off-farm packing facility would be required to establish and implement a food safety plan, we expect that its food safety plan would focus on a few key preventive controls, including some that would have counterparts in the proposed produce safety rule. For example, we expect that the food safety plan for an off-farm packing facility would include preventive controls such as maintaining and monitoring the temperature of water used during packing. These preventive controls would have counterparts under the 2013 proposed produce safety rule (see, e.g., proposed § 112.46(c)). We also expect that an off-farm packing facility would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces. See the discussion in the 2013 proposed preventive controls rule about an outbreak of listeriosis from cantaloupes, which was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (78 FR 3646 at 3814). On-farm packing facilities would be subject to similar, but not identical, requirements (see e.g., proposed § 112.111(b) for cleanliness of food contact surfaces and proposed § 112.113 for protection against contamination).

An off-farm packing facility also would be required to establish and implement appropriate preventive control management components, including monitoring, corrections or corrective actions, and verification as appropriate to the nature of the preventive control, and would establish and maintain records relative to these preventive controls. Some of these management components also would have counterparts under the 2013 proposed produce safety rule (see, e.g., proposed § 112.46(a) and (b)). Moreover, we consider it likely that industry associations and coalitions would develop a generic food safety plan applicable to off-farm packing and holding of produce covered by the produce rule, based in large part on the final provisions of the produce safety rule. An off-farm packing and holding facility would be able to start from such a generic food safety plan, or to start from the provisions of the final produce safety rule, in generating its own food safety plan, and to tailor its own food safety plan to its particular circumstances, such as the commodities it packs and holds.

The FD&C Act makes the status of an establishment as a facility subject to the section 415 registration requirements, rather than a farm, relevant to which requirements apply to packing and holding activities. Section 418(a) of the FD&C Act, which applies to facilities required to register, 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 such facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice. Section 418(h) of the FD&C Act requires the owner, operator, or agent in charge of a facility to 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 (see section 418(h) of the FD&C Act). In contrast, section 419 of the FD&C Act directs FDA (rather than the owner, operator, or agent in charge of a farm) 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 RACs for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death.

VI. Definitions of ''Holding'' and ''Packing''

A. 2013 Proposed Definition of ''Holding''

We proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 (see section V.A).

B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''

We proposed two exemptions directed to facilities ''solely engaged'' in the storage (i.e., holding) of certain types of food, and explained our reasons for doing so.

First, we proposed to exempt facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing from the requirements for hazard analysis and risk-based preventive controls, and explained our reasons for proposing to do so (proposed § 117.5(j); see discussion at 78 FR 3646 at 3709). We intended this provision to 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 the requirements for hazard analysis and risk-based preventive controls, provided that such facilities do not conduct other activities subject to FSMA's requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3709).

Second, we proposed to exempt a ''facility solely engaged in the storage of packaged food that is not exposed to the environment'' from the requirements for hazard analysis and risk-based preventive controls that would be established in subpart C (proposed § 117.7(a); see discussion at 78 FR 3646 at 3713). We intended this provision to exempt, for example, facilities that store packaged food in containers in a warehouse. However, a facility solely engaged in the storage of packaged food that is not exposed to the environment and that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens would be subject to modified requirements (see proposed §§ 117.7(b) and § 117.206).

In this section of this document, we are proposing revisions to the definition of ''holding'' in addition to the revisions, discussed in section V.B.2, that would be conforming amendments in light of the revised ''farm'' definition. In this section of this document, we are reopening the comment period with respect to the revised definition of ''holding'' (proposed § 117.3).

C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing

Some comments support the proposed exemption for a facility solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. However, some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, that the proposed definition of ''holding'' would preclude facilities such as grain elevators from being eligible for the exemption in proposed § 117.5(j) because most such facilities conduct a variety of activities in addition to ''storage.'' For example, comments note that grain elevators typically conduct the following activities that could be characterized as being practical necessities, either for the

purposes of safe or effective storage or for meeting customer specifications:

Fumigate grain to control pest infestation during storage;
Clean grain using various mechanisms (sifting, sieving, and screening);
Convey grain throughout the facility;
Dry grain received with high moisture content; and
Blend lots of grain.

Some comments recommend that we modify the proposed definition for ''holding'' to (1) encompass activities performed for the safe or effective storage of RACs (such as drying, screening, conditioning, and fumigating) off-farm and (2) encompass activities performed on RACs as a practical necessity for product distribution (such as blending different lots of the same commodity to meet a customer's quality specifications).

D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Some comments support the proposed exemption for a facility ''solely engaged in the storage of packaged food that is not exposed to the environment.'' These comments note that warehouses typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of storage or for product distribution, including:

Affix tracking labels;
Transport to a storage location in the warehouse;
Hold non-food products, including toys and beauty aids;
Break down pallets of packaged food for distribution to the retail level in less-than-pallet quantities;
Assemble ''sales kits'' for use in fundraising drives;
Assemble variety packs by packing; and
Use packaged food to build store displays.

Some of these comments recommend that we modify the proposed definition for ''holding'' to encompass activities that are performed on packaged food that is not exposed to the environment (1) incidental to storage of the food (such as transport and storage of non-food products); and (2) as a practical necessity for product distribution (such as affixing tracking labels, breaking down pallets, assembling sales kits and variety packs, and building store displays).

E. Proposed Revisions to the Definition of ''Holding''

Taking into account the comments we have reviewed so far, we tentatively conclude that we should revise the definition of ''holding'' to encompass activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food). In addition to the activities specifically identified in the comments, we are aware of other activities (Ref. 15) that can be considered incidental to storage of RACs, either for the purposes of safe or effective storage or for meeting customer specifications, including:

Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;

Using modified atmosphere treatments to control pests;

Using biological controls for pests;

Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;

Weighing grain;

Sampling and grading grain; and

Aerating grain to control temperature.

The revised definition of ''holding'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. Our previously proposed revisions already included activities traditionally performed by farms and farm mixed-type facilities for the safe or effective storage of RACs (78 FR 3646 at 3681). In this document, we are proposing to revise the definition of holding in all three regulations to:

Clarify that holding also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same commodity));

Broaden ''activities . . . performed for the safe or effective storage of raw agricultural commodities'' to apply to all food, not just RACs;

Broaden ''activities . . . performed for the safe or effective storage'' to apply to all establishments that hold food, not just farms and farm mixed-type activities;

Add ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged food as well as activities conducted on RACs; and

Specify that holding facilities ''could'' include the listed types of facilities to clarify that some of these facilities might not meet the definition of a holding facility if they perform other activities not included in the definition of holding (e.g., if a grain elevator mixes different commodities to prepare animal feed).

As discussed in section V.B.2, the revised definition of ''holding'' also would remove limitations on where the food is grown or raised (as a conforming change to the revised definition of ''farm''). The revised definition of ''holding'' would now be a one-part definition that applies to all facilities that hold food, rather than a two-part definition that first specifies activities that are within the definition regardless of the type of establishment and then specifies additional activities that would apply only to establishments that are farms or farm mixed-type facilities. See the proposed regulatory text for the definition of holding in proposed §§ 1.227, 1.328, and 117.3.

With this revised definition of ''holding,'' facilities such as grain elevators and silos would, in most cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 117.5(j)), because the definition would encompass activities performed as a practical necessity for the distribution of RACs. Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, also may satisfy these criteria for exemption.

With this revised definition of ''holding,'' facilities such as warehouses would, in many cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.7(a)), because the definition would encompass activities that are a practical necessity for product distribution (such as breaking down pallets and affixing tracking labels). We are adding ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged food as well as activities conducted on RACs. Although we are not adding more examples to reflect activities conducted on packaged food, the revised definition of ''holding'' also would include activities such as assembling sales kits and variety packs, because such activities are similar to breaking down pallets except that the order of activities is reversed.

F. Proposed Revisions to the Definition of ''Packing''

Just as there are some activities that are performed incidental to storing a food, there are some activities that are performed incidental to packing a food. For example, sorting, culling, and grading RACs could be an activity

incidental to packing on a farm or farm mixed-type facility, whereas off-farm some sorting or similar activities such as culling or grading may be required to ensure that like items are packed together, or to remove damaged items. As another example, food may need to be conveyed (moved) about an establishment for the purpose of packing it, and may need to be weighed to ensure that appropriate amounts are packed. We tentatively conclude that we should revise the definition of ''packing'' so that it includes activities performed incidental to packing a food. The revised definition of ''packing'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. Our previously proposed revisions already included activities traditionally performed by farms and farm mixed-type facilities for the safe or effective packing of RACs (78 FR 3646 at 3681–3682). In this document, we are proposing to revise the definition of packing in all three regulations to:

Clarify that packing also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading));

Provide that activities performed incidental to packing a food would apply to all establishments that pack food, not just to farms and farm mixed-type facilities; and

Delete the provision, in the 2013 proposed preventive controls rule, that packing would include activities (which may include packaging) traditionally performed on a farm on RACs grown on a farm for storage or transport, because this issue would be addressed in the revised ''farm'' definition.

See the revised regulatory text for the definition of packing in proposed §§ 1.227, 1.328, and 117.3.

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities

A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities

Some comments object to one or more of the 2013 organizing principles. As previously discussed, some comments focused on the distinction (in the ''farm'' definition, and reflected in Organizing Principle No. 4) that conducting packing and holding activities on a farm's own RACs would be within the ''farm'' definition, but conducting packing and holding activities on others' RACs would be outside the ''farm'' definition (see section V.B.1). Other comments focused on Organizing Principle No. 3—i.e., 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 (see section V.C.1). One comment asserts that the 2013 organizing principles rest on a flawed understanding of how farming works because they assume that farms exist simply to grow crops and that getting those crops to market is something that ''farms'' don't do. This comment also asserts that the reality is that a farm cannot stay in business without marketing its crops and preparing those crops for market, and that the imperative to maximize the value a farm receives for its crops creates the need for value-added marketing and cooperative distribution. This comment recommends that we revise the organizing principles to reflect the realities and range of activities that farms do to their crops to prepare those crops and get them to markets.

B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition

We articulated the 2013 organizing principles for classifying on-farm activities to operate within the framework, already established in the section 415 registration regulations, in which an establishment that packs and holds others' RACs would be outside the ''farm'' definition and, thus, be required to register as a food facility. Our proposed revisions to the ''farm'' definition would change that framework and, as a consequence, require that we reconsider those organizing principles.

Organizing Principles Nos. 1, 3 and 5 remain fully consistent with the proposed revisions to the ''farm'' definition. However, there would be no need to specify, in Organizing Principle No. 2, that activities that farms traditionally do relate only to their own RACs. In addition, Organizing Principle No. 4 would no longer apply, because the revised ''farm'' definition would no longer classify an activity as within (or outside of) the ''farm'' definition based, in part, on whether an activity is conducted on a farm's own RACs or on others' RACs. Therefore, we tentatively conclude it is appropriate to delete Organizing Principle No. 4 in light of the proposed revisions to the ''farm'' definition.

Taking into account the comments we have reviewed so far, Table 4 shows our current thinking regarding the organizing principles applicable to the revised ''farm'' definition.

TABLE 4—UPDATED ORGANIZING PRINCIPLES THAT WOULD APPLY TO THE REVISED ''FARM'' DEFINITION

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 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	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.

C. Changes to Classification of On-Farm Activities

We reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. See the Appendix to this document for a comprehensive table comparing the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed preventive controls rule to our current thinking on the classification of these on-farm activities. As can be seen in the Appendix, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed preventive controls rule) that

could be classified in more than one way. For example, in the 2013 proposed preventive controls rule, we classified ''washing'' as a harvesting activity (e.g., if RACs are washed while they are being removed from the field) as well as a manufacturing/processing activity (e.g., during the production of fresh-cut produce). In this supplemental notice of proposed rulemaking, we also consider ''washing'' to be a packing activity (e.g., if RACs are washed in a flume or dump tank located at the farm's packing shed). (Because the definition of manufacturing/processing specifies that for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding, including ''washing'' as an example of a manufacturing/processing activity would not mean that a farm is conducting a manufacturing/processing activity when it washes RACs in its packing shed on its farm, because washing RACs on a farm would be a packing activity.)

See Table 5 in this document for a list of the activity classifications that would change in light of the proposed revisions to the ''farm'' definition and our reconsideration of activity classification. As shown in Table 5, changes in activity classification as a result of the proposed revisions to the ''farm'' definition would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as a food facility. Importantly, the revised ''farm'' definition would not result in any new circumstance where a farm would now be required to register as a food facility.

Table 5 includes one activity (i.e., field coring) that we did not address in the 2013 proposed preventive controls rule. As discussed in section V.C, we are including this activity to make clear that on farm ''field coring'' of produce (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity.

Table 5 includes one activity (i.e., drying/dehydrating (incidental to holding) that we now would classify in fewer ways than we did in the 2013 proposed preventive controls rule. In the 2013 proposed preventive controls rule, we classified drying/dehydrating (for purposes of storage or transport, rather than to create a distinct commodity) (e.g., drying alfalfa) as being either a packing activity or a holding activity, depending on when the drying/dehydrating took place. After reconsidering all of the activity classifications, we tentatively conclude that such drying/dehydrating should continue to be classified as ''holding,'' but does not constitute ''packing.'' We request comment on this narrowed classification of drying/dehydrating when the drying/dehydrating does not create a distinct commodity.

Table 5 includes one activity (i.e., fermenting cocoa beans and coffee beans) that we would now classify differently than we did in the draft risk assessment (issued in conjunction with the 2013 proposed preventive controls rule). In the draft risk assessment (Ref. 16), we classified fermenting cocoa beans and coffee beans as harvesting activities (see Footnote 2 in Table 23 of the draft risk assessment). After reconsidering all of the activity classifications, we tentatively conclude that fermenting cocoa beans and coffee beans should be classified as ''holding'' rather than as ''harvesting,'' because fermentation generally happens after cocoa beans and coffee beans are removed from the plants. We request comment on this reclassification of fermenting cocoa beans and coffee beans.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION

Activity	Classified in 2013 proposed preventive controls rule	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed preventive controls rule? [2]
Cooling	Harvesting; (§ 117.3); Mfg [1]/Processing (§ 117.3).	• Harvesting (e.g., hydro-cooling leafy vegetables in the field). • Packing (e.g., hydro-cooling in a packing shed) • Holding (e.g., cold storage) • Mfg/processing (e.g., refrigeration of processed food)	Acknowledge that cooling can occur during many farm operations.
Drying/dehydrating (incidental to holding).	Packing or Holding (Tables 4 and 5).	• Holding (e.g., drying hay or alfalfa)	Because we would no longer consider drying/dehydrating to be a packing activity.
Drying/dehydrating to create a distinct commodity (transforms a RAC into a processed food).	Mfg/Processing (Tables 4 and 5).	• Mfg/processing (e.g., drying grapes to create raisins, and drying herbs to create a distinct commodity) (because it transforms a RAC into a processed food) (but allowed within the farm definition).	Because we are including this specific mfg/processing activity within the ''farm'' definition, provided that there is no additional manufacturing/processing.
Fermenting cocoa beans and coffee beans.	Harvesting (Footnote 2 in Table 23 of the draft Risk Assessment (Ref. 16)).	• Holding	Because fermentation generally happens after cocoa beans and coffee beans are removed from the plants.
Field coring	N/A [3]	• Harvesting (e.g., coring lettuce in the field)	Because FDA is addressing the activity for the first time.
Filtering	Harvesting (§ 117.3)	• Harvesting (e.g., filtering honey) • Packing (e.g., before packing honey)	Acknowledge that filtering can occur during more than harvesting operations.
Removing stems and husks.	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	Acknowledge that removing stems/husks can occur during more than harvesting operations.
Sifting	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	Acknowledge that sifting can occur during more than harvesting operations.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION—Continued

Activity	Classified in 2013 proposed preventive controls rule	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed preventive controls rule? [2]
Using pesticides in wash water.	Harvesting (Table 5) ..	• Harvesting (e.g., in the field) ..... • Packing (e.g., in a packing shed)	Acknowledge that using pesticides in wash water can occur during more than harvesting operations.
Washing	Harvesting (§ 117.3), and Mfg/Processing (§ 117.3).	• Harvesting (e.g., in the field) ..... • Packing (e.g., in a dump tank or flume in the farm's packing shed) • Mfg/processing (e.g., during production of fresh-cut produce)	Acknowledge that washing can occur during packing operations.

[1] Mfg = Manufacturing

[2] This table focuses on any change in classification in this document compared to the classification, in the 2013 proposed preventive controls rule, for activities conducted on a farm's own RACs. The proposed revisions to the ''farm'' definition would make the distinction between whether a farm conducted an activity on its own RACs or on others' RACs irrelevant.

[3] N/A = Not applicable.

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

A. The 2013 Proposed Exemptions

In the 2013 proposed preventive controls rule, we described provisions of FSMA that direct us to (1) conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the ''farm'' definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3674 and 3689–3691); and (2) consider the results of that science-based risk analysis and exempt facilities that are small or very small businesses from these requirements (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of on-activities that we determine to be low risk involving specific foods that we determine to be low risk. Consistent with this statutory direction, we developed the draft risk assessment and made it available for public comment (Ref. 16 and 78 FR 3824) and proposed three exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed §§ 117.5(g), (h)(1), and (h)(2)).

B. Comments on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

Some comments request clarification on whether an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. Other comments recommend including additional on-farm packing and holding activity/food combinations, or on-farm manufacturing/processing activity/food combinations, as low-risk activity/food combinations eligible for inclusion in the proposed exemptions.

We are confirming that an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. The regulatory text is written in the plural (e.g., ''if the only packing and holding activities . . . that the business conducts are the following low-risk packing or holding activity/food combinations''; and ''if the only manufacturing/processing activities . . . that the business conducts are the following'').

We have not yet completed either our review of comments asking us to include additional activity/food combinations in the proposed exemptions or our analysis of whether each of the recommended additions would satisfy the criteria, described in the draft risk assessment, for a low-risk activity/food combination. However, based on our experience with the draft risk assessment, and the similarity of some of the recommended activity/food combinations to activity/food combinations we evaluated in the draft risk assessment, we consider it likely that we will, after fully considering comments, include additional activity/food combinations in these exemptions when we issue the final rule.

C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

The proposed revisions to the definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing,'' if finalized, would have three principal effects on the proposed exemptions.

First, the proposed exemption for on-farm packing or holding of food by a small or very small business would no longer identify any packing or holding activities for any RACs, because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. The proposed exemption would continue to apply to on-farm packing and holding of processed foods (e.g., packing and holding of hard candy, fudge, taffy and toffee when conducted by a farm mixed-type facility).

Second, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would no longer distinguish between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility's own RACs.

Third, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would be revised to eliminate activities, conducted on others' RACs, which would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding. For example, mixing different lots of the same RACs (e.g., cocoa beans, coffee beans, intact fruits and vegetables, grain, honey, maple sap, and peanuts and tree nuts) would remain within the ''farm'' definition, and not be considered manufacturing/processing, regardless of whether the RACs being mixed are the farm's own RACs or others' RACs.

However, mixing grain products and maple syrup (which are processed foods rather than RACs) would be considered manufacturing/processing and, thus, would continue to be considered a low-risk manufacturing/processing activity listed within the exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business.

We will update these proposed exemptions when we issue the final rule, after considering comments, and reaching a decision in light of those comments, on the proposed revisions to the definitions that impact the proposed exemptions for low-risk activity/food combinations.

IX. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

A. 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

In general, in the 2013 proposed preventive controls rule we proposed that the owner, operator, or agent in charge of a facility:

Prepare and implement a food safety plan, which would include documentation such as a written hazard analysis and various written procedures;

Conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards to determine whether there are hazards that are ''reasonably likely to occur'';

Identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified as ''reasonably likely to occur'' will be significantly minimized or prevented;

Establish a written recall plan for food with a hazard identified as ''reasonably likely to occur'';

Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed;

Establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented;

Take appropriate 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;

Conduct certain verification activities; and

Establish and maintain certain records.

These proposed provisions applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood (21 CFR part 123) and juice (21 CFR part 120)—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on CCPs to control hazards that are ''reasonably likely to occur.''

B. Comments on the ''Reasonably Likely To Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

Some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, about including the ''reasonably likely to occur'' approach in the 2013 proposed preventive controls rule. Some comments express concern that using the phrase ''reasonably likely to occur'' in two different contexts (i.e., within our HACCP regulations as well as in our proposed preventive controls regulations) would be confusing. Some comments assert that the ''reasonably likely to occur'' approach was already so closely linked to our HACCP regulations that the 2013 proposed preventive controls rule would be interpreted as requiring that all necessary preventive controls be established at CCPs. These comments note that such an interpretation would be inconsistent with FSMA. For example, FSMA 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) (section 418(c) of the FD&C Act). In addition, the definition of ''preventive controls'' in FSMA is broader than CCPs (section 418(o)(3) of the FD&C Act). The comments ask that we more explicitly provide for implementation of a range of preventive controls (not just at CCPs.) These comments also express concern that a facility that already had established controls to address hazards—but not at CCPs—would need to revise its food safety plan and re-create any applicable records (e.g., various written procedures) to satisfy the recordkeeping requirements of the rule, which would add costs but no food safety benefits. Some comments suggest that the framework be clearer that the requirements for preventive controls apply to hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.

Other comments on the overall framework for hazard analysis and risk-based preventive controls express concern that the regulatory text, as proposed, would limit a facility's flexibility to develop and implement a food safety system that was indeed risk-based. For example, some comments assert that regulatory text such as ''[p]reventive controls must include, as appropriate to the facility and the food'' appears to provide flexibility, but the practical effect of the term ''must'' preceding the phrase ''include, as appropriate to the facility and the food'' is to remove any flexibility as to what preventive controls must be established and implemented. As another example, these comments emphasize that the proposed requirements did not sufficiently emphasize the risk-based nature of each component of the overall framework for hazard analysis and preventive controls, including monitoring, corrective action procedures, and verification activities, in addition to the hazard analysis and preventive controls. In general, these comments recommend that we provide greater flexibility to manage the control of hazards based on an assessment of both the severity of the hazard and the probability that the hazard will occur in the absence of preventive controls and that we recognize the role of prerequisite programs in the management of hazards. (One definition of ''prerequisite program'' is the ''procedures, including good manufacturing practices, that address operational conditions providing the foundation for the HACCP system'' (Ref. 17).)

C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

The 2013 proposed preventive controls rule would not have required that all preventive controls be established at CCPs. However, we acknowledge that it could be confusing to use the same phrase ''reasonably likely to occur'' in both our HACCP regulations and in the regulations we are proposing to establish to implement FSMA's requirements for hazard analysis and risk-based preventive controls, because the phrase ''reasonably likely to occur'' has been used as the basis for determining hazards that need to be addressed in a HACCP plan at CCPs.

Likewise, the 2013 proposed preventive controls rule would not have limited a facility's flexibility to develop and implement a food safety system that was indeed risk-based. However, we acknowledge that some specific changes to the proposed regulatory text could help to clarify the risk-based nature of all provisions of subpart C.

We have not used the term ''prerequisite program'' in the proposed regulatory text because, like ''hazard reasonably likely to occur,'' it has a connotation with respect to our seafood and juice HACCP programs, that is, it connotes activities that a facility may do that have an impact on product safety but which are outside the scope of the regulatory program. However, comments are not suggesting that prerequisite programs that are essential to ensuring food safety should be outside the scope of this proposed regulatory scheme. In fact, comments asking that we recognize the role of prerequisite programs in the management of hazards point out that preventive controls include control measures that do not include CCPs and that companies would consider many of these to be prerequisite programs. We acknowledge that oftentimes preventive controls, other than those at critical control points, are important parts of a food safety system, and must therefore be included in the food safety plan that would be required by this proposed rule. We attempted to make that clear in the proposed requirement for preventive controls in § 117.135(a) by incorporating reference to ''controls, other than those at critical control points, that are necessary for food safety.''

We did not intend to require that a facility re-create or duplicate existing records associated with controls; we simply laid out in the 2013 proposed preventive controls rule the activities for which we expect there to be records and the information we expect to find in those records.

Taking into account the comments we have reviewed so far, we are proposing a series of revisions to proposed subpart C and are reopening the comment period specifically with respect to these proposed revisions. These proposed revisions include:

Eliminating the term ''hazard reasonably likely to occur'' throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term).

Adding a new defined term, ''significant hazard,'' and, in general, using this new term instead of ''hazard reasonably likely to occur'' throughout the proposed regulations. ''Significant hazard'' would mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.

Defining ''known or reasonably foreseeable hazard'' in place of ''reasonably foreseeable hazard'' and clarifying that the new term means a hazard ''that has the potential to be associated with the facility or the food'' rather than ''a potential . . . hazard that may be associated with the facility or the food'';

Providing additional flexibility to address concerns about re-writing existing plans or programs to conform with the requirement of the preventive controls rule by explicitly providing that:

Preventive controls include controls, other than those at critical control points, that knowledgeable persons commonly recognize as appropriate for food safety;

The preventive control management components (i.e., monitoring, corrective actions, and verification) depend on the nature of the control; and

The recordkeeping requirements do not require duplication of existing records if those records contain all of the required information and satisfy the recordkeeping requirements of the regulation. Existing records may be supplemented as necessary to include all of the required information. In addition, the required information does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by the preventive controls rule may be kept either separately or combined with the existing records.

The framework provided by ''significant hazard'' would reflect a two-part analysis on the part of a facility. First, the facility would narrow ''hazards'' to those hazards that are known or reasonably foreseeable—i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food as well as components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.

The framework established by ''significant hazard'' also would incorporate the concept of risk by specifying that ''significant hazards'' are based on the outcome of a hazard analysis. The hazard analysis would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk—i.e., the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

See the revised regulatory text for the proposed new definition of ''significant hazard'' (proposed § 117.3). The term ''significant hazard'' has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs. However, this term is not used in the seafood, juice or meat and poultry HACCP regulations, which focus on ''hazards reasonably likely to occur.'' We request comment on both the proposed name of the term and the proposed meaning of the term. See also the proposed new provision for the use of existing records (proposed § 117.330, which would be established in subpart F). Table 6 provides some examples of the flexibility that a facility would have in complying with the revised requirements that would be established in subpart C.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C

Flexibility related to . . .	Example
Controls other than those at CCPs	Dividing a facility into zones based on the risk with respect to contamination of product can be a preventive control, but would not be required to have a CCP.
Controls other than those at CCPs	Preventive maintenance that inspects and changes chopper blades on a regular intervals may be considered a preventive control in some instances but would not be required to have a CCP.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C—Continued

Flexibility related to . . .	Example
Circumstances that do not require process controls	Preventive controls for allergen cross-contact.
Circumstances that do not require process controls	Supplier controls.
Monitoring activity that generally would not require monitoring records	Monitoring for foreign material with x-rays.
Corrections that generally would not require records	Re-cleaning and sanitizing inadequately cleaned food contact surfaces before start up.
Preventive controls that would not require validation	Zoning controls.
Preventive controls that would not require validation	Segregation of allergens during storage.
Preventive controls that would not require validation	Training.
Preventive controls that would not require validation	Preventive maintenance.
Preventive controls that would not require validation	Refrigerated storage.
Corrective action that generally would not require verification	Replacement of equipment.

X. Potential Requirements for Product Testing and Environmental Monitoring

A. Our Request for Comment on Including Requirements for Product Testing and Environmental Monitoring in a Final Rule

In the 2013 proposed preventive controls rule, we described the statutory framework of FSMA for product testing and environmental monitoring as verification measures. We also requested comment on when and how product testing programs and environmental monitoring are an appropriate means of implementing section 418 of the FD&C Act (78 FR 3646 at 3762–3765). We specifically requested comment on including requirements for product testing programs and environmental monitoring in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. Our discussions and questions about ''product testing'' focused on ''finished product testing.'' The Appendix contained extensive background on the role of testing as a verification measure in a modern food safety system (78 FR 3646 at 3812–3820; see also the corrected Appendix, 78 FR 17142 at 17143 to 17151).

B. Product Testing

1. Comments on Product Testing

Some comments support product testing as a verification activity and make recommendations for what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan. Some of these comments emphasize that product testing would not be appropriate as a control measure. Other comments do not support including requirements for ''finished product testing'' as a verification measure, but support including requirements for ''product testing'' in the final rule if the focus is broader than ''finished product testing,'' the use of product testing is tied to risk, and the regulations provide flexibility in how product testing is used in a food safety plan. Some comments assert that product testing is required by section 418 of the FD&C Act and that it is an appropriate means of verifying overall control, especially for products that support pathogen growth. In the following paragraphs, we describe some of the key recommendations in the comments regarding what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan.

Some comments recommend that product testing include testing raw materials and ingredients, as well as in-line testing of product during production. Some comments recommend that requirements encompassing more than ''finished product testing'' would provide facilities with the flexibility to establish a risk-based testing program. For example, a facility that adds seasoning to chips after the chips have been cooked using a process that would significantly minimize pathogens may conclude that testing the seasoning used as an ingredient would be a more appropriate verification activity than testing finished product (i.e., the chips with the added seasoning). These comments also assert that requirements for ''product testing'' would be more consistent with the statutory direction in section 418 of the FD&C Act than requirements for ''finished product testing.''

Some comments that emphasize the risk-based nature of any requirements for product testing assert that product testing may be of limited value for a product that will undergo a ''kill step'' (a treatment to significantly minimize pathogens) later in processing or that does not support the survival or growth of environmental pathogens (because such organisms are unlikely to pose a risk in the finished food). Other comments note that product testing would not be appropriate for certain types of facilities, such as distributors. Some comments question whether product testing would be appropriate for products with a short shelf life (such as produce).

Some comments identify circumstances where product testing would—or would not—be appropriate to include as a verification activity in a food safety plan. For example, comments state that product testing would be an appropriate verification activity to include in a food safety plan in plants that produce high-risk products; when there is a risk of contamination of the product or product contact surfaces; when the outcome of a hazard analysis demonstrates that a hazard can remain or be placed on ready-to-eat (RTE) products; when an environmental pathogen is considered a hazard reasonably likely to occur; when a positive result is obtained as a result of environmental monitoring; after a corrective action has been implemented (such as after a product has been reworked because it tested positive for a pathogen); and in circumstances where testing is the only practical way to verify the absence of a contaminant (such as aflatoxin). Some comments state that product testing would not be an appropriate verification activity to include in a food safety plan if a positive result from environmental monitoring is found on a non-product-contact surface.

Some comments recommend written procedures for product testing. Some of these comments emphasize that any requirements for such written procedures should not be prescriptive.

Some comments question whether it would be appropriate to require product testing in light of known limitations such as those discussed in section I.F of the Appendix. For example, 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. Moreover, these comments point out that 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 (78 FR 3646 at 3819). Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for product testing for consideration.

2. Potential Requirements for Product Testing

We acknowledge that there are limitations to product testing. Nonetheless, product testing programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for product testing. Such requirements would be tied to risk and addressed through flexible written procedures that would address both test procedures and corrective action plans.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how product testing programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for product testing should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if included in a final rule, establish requirements for:

Product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control (proposed § 117.165(a)(2));

Written procedures for product testing (proposed § 117.165(b)(2));

Corrective action procedures for product testing (proposed § 117.150(a)(1)(ii)(A)); and

Records of product testing (proposed § 117.155(b));

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. Consistent with the requests of the comments, the proposed regulatory text would provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate by providing that the facility can take into account the facility, the food, and the nature of the preventive control (e.g., whether the control is a kill step) rather than prescribe product testing in specific circumstance, or require that all types of facilities (including warehouses) conduct product testing. For supplementary information relevant to product testing, see the 2013 proposed preventive controls rule (78 FR 3646 at 3763–3764), the corrected Appendix (78 FR 17142 at 17143 to 17151), and Ref. 18.

C. Environmental Monitoring

1. Comments on Environmental Monitoring

Some comments support environmental monitoring as a verification activity. In general, these comments recommend that the final rule specifically require environmental monitoring when RTE product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. Comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk.

Some comments that generally support environmental monitoring as a verification activity nonetheless express concern about the potential for such requirements to be overly prescriptive. Comments particularly express concern about potentially prescriptive requirements for corrective actions if an environmental pathogen or appropriate indicator organism is detected. Some comments express concern about how potentially prescriptive requirements would impact products (such as produce) with a short shelf life.

Some comments do not support including requirements for environmental monitoring as a verification measure. Some of these comments assert that requirements for environmental monitoring would not be in accord with guidelines issued by the Codex Alimentarius Commission (Codex). Some comments note that environmental monitoring would not be relevant to all products, such as products that will be heat-treated or otherwise subject to a kill-step. Other comments note that environmental monitoring would not be relevant to facilities such as food distributors, due to the low likelihood of product contamination occurring in storage and distribution centers. Some of these comments express concern about broad requirements that would require environmental monitoring in a manner that was not risk-based, such as when an environmental pathogen is not reasonably likely to occur. Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for environmental monitoring for consideration.

2. Potential Requirements for Environmental Monitoring

Although the HACCP Annex of the Codex General Principles of Food Hygiene (Ref. 19) does not specifically recommend environmental monitoring as a verification activity in HACCP systems, the Codex General Principles of Food Hygiene (Ref. 20) does indicate that sanitation systems should be monitored for effectiveness and periodically verified, where appropriate, by microbiological sampling of environment and food contact surfaces, and regularly reviewed and adapted to reflect changed circumstances. Environmental monitoring is recommended in Codex Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods (see Annex I) (Ref. 21) and the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (see Annex III) (Ref. 22). Moreover, currently available data and information support the role of environmental monitoring in a food safety system that incorporates hazard analysis and risk-based preventive controls. (See, e.g., the 2013 proposed preventive controls rule (78 FR 3646 at 3764–3765), the corrected Appendix (78 FR 17142 at 17143 to 17151), and (Ref. 23). Environmental monitoring programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for environmental monitoring. The potential requirements would provide flexibility for facilities to tailor their environmental monitoring programs based on risk. Environmental monitoring would be required in the specific circumstances where RTE product is exposed to the environment prior to packaging and the packaged

food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. However, the potential requirements would not otherwise specify circumstances where environmental monitoring would be required and would instead require that the facility conduct environmental monitoring as appropriate to the facility, the food, and the nature of the preventive control. The potential requirements would also not be prescriptive in the types of corrective actions needed in response to detecting an environmental pathogen or appropriate indicator organism in the environment; they would provide flexibility for facilities to establish and implement written corrective action procedures to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how environmental monitoring is an appropriate means of implementing FSMA. We are seeking comment on whether requirements for environmental monitoring should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if included in a final rule, establish requirements for:

Performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen (proposed § 117.130(c)(1)(ii));

Environmental monitoring, for an environmental pathogen (e.g., *L. monocytogenes*) or for an appropriate indicator organism (e.g., Listeria spp.), as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control, if contamination of an RTE food with an environmental pathogen is a significant hazard (proposed § 117.165(a)(3));

Records of environmental monitoring (proposed § 117.155(b));

Written procedures for environmental monitoring (proposed § 117.165(b)(3)); and

Corrective action procedures for environmental monitoring (proposed § 117.150(a)(1)(ii)(B)).

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. For supplementary information relevant to environmental monitoring programs, see the 2013 proposed preventive controls rule (78 FR 3646 at 3764–3765), the corrected Appendix (78 FR 17142 at 17143 to 17151), and Ref. 23.

XI. Potential Requirements for a Supplier Program

A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

In the 2013 proposed preventive controls rule, we described the statutory framework of FSMA for supplier controls—i.e., the supplier verification activities that section 418 of the FD&C Act includes as an example of preventive controls. We also requested comment on when and how supplier verification activities are an appropriate means of implementing section 418 (78 FR 3646 at 3763–3767). We specifically requested comment on including requirements for supplier approval and other verification activities in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. The Appendix contained extensive background on the role of supplier programs in a modern food safety system (78 FR 3646 at 3820–3821; see also the corrected Appendix, 78 FR 17142 at 17151 to 17152).

B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

Some comments support including requirements for a supplier program in a final rule. These comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk, including risk inherent to raw materials and ingredients and risk that may be associated with a particular supplier (e.g., as reflected by the supplier's performance history). These comments provide many specific recommendations for what such requirements should—and should not—include. We summarize these recommendations in Table 7.

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM

Most comments support a requirement:	Most comments do not support a requirement:
For receiving raw material and ingredients from approved suppliers	For a written list of approved suppliers (because the list would be subject to frequent (perhaps daily) change).
For verification of a facility's immediate supplier	For verification of the supplier's supplier (because the facility has the greatest knowledge, leverage and ability to conduct meaningful oversight of its immediate supplier and because it is the supplier who is accountable to verify back one more step).
For records documenting that the basic requirements are being carried out.	For documents such as an underlying audit report (because of concerns about confidential information).
For audits as a verification activity, provided that the requirements are flexible and audits are not over-emphasized at the expense of other verification activities.	Prescribing the frequency of audits (particularly an annual frequency) (because an audit is only one tool and audits should be based on risk and on the performance of the supplier).
Limiting a supplier program to facilities that manufacture or process food.	Specifying that some hazards require more than one verification activity (because doing so would be too prescriptive and would not allow the facility the flexibility to determine the appropriate risk-based approach).
For oversight of a supplier program by a qualified individual	For a receiving facility to identify the regulations to which the supplier is subject (because the distinction would not be material to food safety).
That would be consistent with the Foreign Supplier Verification Program being established in a separate rulemaking	

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM—Continued

Most comments support a requirement:	Most comments do not support a requirement:
Specifying that a supplier program may be managed at a corporate level (rather than by specific facilities), because supplier programs are often managed at the corporate level. Some comments specifically recommend that inspection of a supplier program take place at the location where the program is managed, including at a corporate location rather than at an individual facility.	

Comments also address several other issues, such as whether the final rule should:

Be limited to circumstances where a hazard is controlled by the supplier, or be required even if the hazard would be controlled by the receiving facility or by the receiving facility's customer.

Include requirements for specific types of verification activities based only on the seriousness of hazards. Although some comments support such requirements, other comments do not because the basis should be risk (which includes probability as well as severity).

Allow substitution of an inspection (e.g., by FDA) for an audit. Although some comments support such a substitution, others do not because they assert that an inspection and an audit are different in nature.

Require a receiving facility to consider relevant regulatory information about the supplier. Although some comments support such requirements, others do not (e.g., because the information (which can be part of an overall supplier assessment) may not be available in a timely manner, is narrow in scope, and would diminish the importance of the supplier's food safety plan and the effectiveness of its implementation).

Include requirements related to supplier non-conformance. Although some comments support such requirements, others maintain that supplier non-conformance would be better suited to guidance. Some comments specifically oppose a requirement for ''discontinuing use of the supplier'' and recommend flexibility for how a receiving facility would address supplier non-conformance.

Provide for alternative verification requirements when a supplier is a qualified facility (which is subject to modified requirements; see proposed § 117.201 in the 2013 proposed preventive controls rule). Although some comments support alternative requirements for suppliers that are qualified facilities, others express concern about whether alternative requirements can be practically implemented. Some comments state that the supplier verification requirements should not prevent facilities from sourcing ingredients from suppliers that are qualified facilities.

In general, comments that simply oppose including a supplier program in the final rule express concern about cost, ingredient diversity, and duplication of efforts. Some of these comments recommend that we issue guidance on supplier verification activities rather than establish requirements in the final rule. Some commenters, including those with varying views about the issue, nonetheless requested that FDA propose regulatory language for consideration.

C. Potential Requirements for a Supplier Program

Section 418 of the FD&C Act specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act), Supplier controls, when implemented appropriately, are an important preventive control that can ensure that significant hazards will be significantly minimized or prevented for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for a supplier program as a preventive control. In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how supplier programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for a supplier program should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed FSVP rule. In that supplemental notice we request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and preventive controls supplier verification provisions—as well as other aspects of the FSVP and preventive controls regulations—should be aligned in the final rules.

See the proposed regulatory text (proposed § 117.136 and the applicable definitions in proposed § 117.3) for the full text of such potential requirements. Briefly, the proposed regulatory text would, if included in a final rule:

Establish definitions for terms used in the potential requirements for a supplier program (i.e., receiving facility; supplier; and qualified auditor) (proposed § 117.3)

Establish a risk-based requirement for a written supplier program that:

Would require, with some exceptions, a supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of raw material or ingredient (proposed § 117.136(a)(1) and (2); and

Would not apply to raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance (proposed § 117.136(a)(1)(ii));

Require verification activities, as appropriate to the hazard, and documentation of such activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 117.136(a)(3)(i));

Require verification activities to verify that the hazard is significantly minimized or prevented, the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, and the incoming raw material or ingredient is

produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 117.136(a)(3)(ii));

Provide flexibility for a receiving facility to determine and document the appropriate verification activities for raw materials and ingredients from particular suppliers, based on a series of factors, except when there is a reasonable probability that exposure to a significant hazard will result in serious adverse health consequences or death to humans (proposed §§ 117.136(b) and 117.136(c)(1)) (see next bullet);

Require an annual audit as a verification activity when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, unless the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (proposed § 117.136(c)(2));

Provide for an alternative verification activity when the supplier is a qualified facility (proposed § 117.136(c)(3));

Provide for alternative verification activities when the supplier is a farm that would not be subject to the requirements in the final produce safety rule under proposed § 112.4 (proposed § 117.136(c)(4));

Require that an audit be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function (proposed § 117.136(d)(1)) and proposed § 117.180);

Provide that inspection by FDA or an officially recognized or equivalent food safety authority may substitute for an audit (proposed § 117.136(e));

Require action to address supplier non-conformance (proposed § 117.136(f)); and

Require documentation of verification activities in records (listed in proposed § 117.136(g)), including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier's relevant food safety records (proposed § 117.136(g)(5), (6), and (7), respectively).

In addition, the potential addition of requirements for a supplier program would require conforming amendments to other provisions of the rule, including the requirements for a food safety plan, preventive controls, validation, verification of implementation and effectiveness, and the list of implementation records for subpart C (see proposed §§ 117.126(b)(3), 117.135(c)(4), 117.140(b), 117.160(b)(3), 117.165(a)(4), and 117.190(a)(4), respectively). For supplementary information relevant to a supplier program, see the 2013 proposed preventive controls rule (78 FR 3646 at 3765–3767), the corrected Appendix (78 FR 17142 at 17151- 17152), and Ref. 24. In the following paragraphs, we provide additional information about the potential proposed requirements for a supplier program.

Reflecting the risk-based (including severity as well as probability) nature of a supplier program, a receiving facility's program would be limited to those raw materials and ingredients for which the receiving facility has identified a significant hazard. As discussed in section IX.C, ''significant hazard'' would be defined in the rule. Under the definition, hazards are determined to be significant based on the outcome of a hazard analysis and, thus the determination would incorporate the concept of risk. In addition, a receiving facility would establish and implement a supplier program only when a significant hazard is controlled before receipt; a receiving facility would not be required to establish and implement a supplier program if the receiving facility, or the receiving facility's customer, controls the hazard (and the customer provides assurances as to the control). Under this risk-based approach, a processor of fresh-cut produce generally would be required to establish a supplier program for hazards associated with the fresh produce it processes (which would be controlled by the supplier during growing and harvesting), but a manufacturer of an acidified food would not be required to establish a supplier program for peppers that it uses to produce salsa if it will control any significant hazard for the peppers during manufacture of the salsa.

The potential supplier program would include requirements applicable to a ''receiving facility'' and the proposed definition of ''receiving facility'' would describe a receiving facility as a facility that manufactures/processes a raw material or ingredient that it receives from a supplier. A supplier would be defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consist solely of the addition of labeling or similar activity of a *de minimis* nature. The supplier could be an ''establishment'' rather than a ''facility'' because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a ''facility'' as that term would be defined for the purpose of this rule. Under this definition, a facility that packs or holds the food without any type of manufacturing/processing would not be a supplier. Under this approach, a facility would not be required to establish a supplier program for food products that it only packs or distributes. For example, a receiving facility might receive a raw material or ingredient from a distribution center that receives the raw material or ingredient from a manufacturing facility or a farm. The distribution center, which is the immediate previous source of the raw material or ingredient, would not be required to establish a supplier program and would not be considered the supplier; rather the supplier would be the manufacturer or the farm (which manufactured/processed the food or harvested the food that was provided to the distribution center and subsequently to the receiving facility). In such instance, if the receiving facility has identified a significant hazard for the raw material or ingredient, and that hazard is controlled by the supplier (the manufacturer or the farm), the receiving facility would establish verification activities related to the manufacturer or the farm that provided the raw material or ingredient to the distribution center.

If a facility receives an ingredient from a supplier, but the control of the hazard is by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard, i.e., the receiving facility would review the supplier's food safety records for its supplier's control of the hazard. For example, if a salad manufacturer is receiving cut produce such as celery from a fresh-cut produce supplier that receives celery from a farm, the salad manufacturer could conduct verification activities related to the on-farm controls by reviewing the supplier program of, and verification activities conducted by, the fresh-cut produce supplier for its supplier, the farm (in addition to verifying the fresh-cut produce supplier's control of pathogens).

We understand that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributers, between a receiving facility and the establishment that would be considered the supplier, which would make

supplier verification very challenging under certain circumstances. However, we believe that supplier verification is very important for RACs, in particular produce that will be further processed or consumed without a treatment that will significantly minimize or prevent pathogens. We request comment on what verification activities would be appropriate for receiving facilities to conduct when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. For example if a receiving facility is a fresh-cut processing facility that receives produce from a distributor, who receives produce from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms where the hazards are being controlled, what supplier controls should be applied for the produce coming from the farms? We request comment on whether and how the requirements for supplier verification should address such situations.

In addition, we seek comment regarding whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain (e.g., by Supplier A, a farm), and Point B in the supply chain is a facility (such as Warehouse B, Distributor B, or Packing Shed B) that only packs or holds food, but does not manufacture/process food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain, which also would not be required to have a supplier program (e.g., Retail Food Establishment C or Consumer C). For example, if Packing Shed B distributes produce it packs after receiving the produce from Farm A directly to retail facilities (which would not be subject to the requirements of this preventive controls rule), no supplier controls would be applied to Farm A. Should verification activities be required in circumstances in which a RAC such as fresh produce will not be sent to any facilities that would be required to have preventive controls before reaching consumers?

The potential supplier program would be included in the food safety plan and, thus, would be prepared (or overseen) by a qualified individual (see proposed § 117.126(b)(7)). A supplier program could be established and maintained by a facility's corporate headquarters or parent entity. The recordkeeping requirements would specify that electronic records are considered to be onsite if they are accessible from an onsite location, and we expect that many records for the supplier program would be in electronic form (and thus easily retrievable by a facility during an inspection).

Rather than specifically require a written list of approved suppliers, the potential requirements would specify that the supplier program be written and include verification activities, as appropriate to the hazard, and documentation of such activities, to ensure products are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use). Such a program could include, for example, written procedures for approving suppliers, for approving (or rejecting) specific raw materials and ingredients, and for documenting that raw materials or ingredients are only received from approved suppliers. The potential requirements would recognize that there can be circumstances that would require a facility to receive raw materials or ingredients on a temporary basis from an unapproved supplier (e.g., if there is a disruption in delivery of raw materials and ingredients from approved suppliers due to circumstances such as localized flooding or malfunctioning equipment). We request comment on examples of circumstances when it would be necessary and appropriate to receive raw materials and ingredients on a temporary basis from an unapproved supplier and on the types of verification activities that a facility should conduct on food from an unapproved supplier.

The potential requirements would provide flexibility for the verification activities that the receiving facility would conduct for raw materials and ingredients. With one exception, the receiving facility would have flexibility to select one or more of four possible activities: (1) onsite audit; (2) sampling and testing of the raw material or ingredient, which could be conducted by either the supplier or the receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; and (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier. To determine which option is appropriate, the receiving facility could consider (1) the severity of the hazards; (2) where the preventive controls for those hazards are applied (such as at the supplier or the supplier's supplier); (3) the supplier's procedures, processes, and practices related to the safety of the raw materials and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food; (5) the supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation. Thus, a receiving facility would have flexibility to select a verification activity based on the circumstances.

The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. In this circumstance, under the potential supplier program, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. The potential requirement for an annual audit is limited to when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. Further, the receiving facility could select less frequent audits or a different verification activity, if it documented its determination that the less frequent onsite auditing or other verification activity provides adequate assurance that the hazards are controlled. The potential recordkeeping requirements that would apply to audits would identify specific information that the records must provide about the audit, including the conclusions of the audit, but would not specify that the underlying audit report is part of the required documentation of an audit.

A person who conducts an audit would need to be qualified to do so. To be qualified, a person who conducts an audit (''qualified auditor'') would be required to satisfy the criteria for a ''qualified individual'' (a person who has successfully completed training in the development and application of risk-based preventive controls equivalent to that of an FDA-recognized standardized curriculum or is otherwise qualified through job experience to develop and apply a food safety system) and have technical expertise obtained

by a combination of training and experience appropriate to perform the auditing function.

The potential supplier program would require the receiving facility to know the FDA food safety regulations that apply to the supplier, and relevant information about the supplier's compliance with those regulations. The focus of section 418 of the FD&C Act is on preventing food safety problems rather than on reacting to them. Section 418 of the FD&C Act requires the owner, operator, or agent in charge of a facility to establish and implement preventive controls to significantly minimize or prevent known or reasonably foreseeable hazards. By specifying that supplier verification activities are a preventive control, section 418 requires the receiving facility to take necessary actions to ensure that raw materials and ingredients are not adulterated. To determine whether incoming raw materials and ingredients are adulterated, a receiving facility would need to know the regulatory framework that applies to the raw materials and ingredients, and to have confidence that its supplier is complying with that regulatory framework.

The potential supplier program would include provisions to address non-conformance by a supplier. This potential requirement would not prescribe when a particular corrective action (such as discontinuing a supplier) is necessary. A facility could substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit. Even though inspection procedures and audit procedures are not identical, we tentatively conclude that a facility should have flexibility to determine whether an inspection could substitute for an audit based on characteristics such as the severity of the hazard, how the supplier controls the hazard, and the supplier's performance history. For example, a facility that receives pickles from a facility subject to the acidified foods regulations in 21 CFR 114 may conclude that an FDA inspection for compliance with acidified foods regulations (concluding that no action is indicated) provides adequate assurance that the facility is producing pickles in compliance with the requirements of applicable FDA food safety regulations and that the pickles are not adulterated under section 402 of the FD&C Act. For additional discussion of our reasons for tentatively concluding that it would be appropriate to substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit, see the discussion in the proposed FSVP rule (78 FR 45730 at 45758). In addition, we are asking for comment on whether it would be appropriate to substitute an inspection in another country (Country A) for an audit when, for example, it is the food safety authority of Country B (whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) that conducted the inspection in Country A.

The potential requirements would provide for alternative verification requirements when a supplier subject to the requirements of section 418 of the FD&C Act is a qualified facility subject to modified requirements. Section 418 provides different requirements for qualified facilities, which are reflected in the different potential verification requirements for such facilities. Although the potential requirements would allow a receiving facility to conduct an alternative verification activity when the supplier is a qualified facility, they would not require this.

Likewise, the potential requirements would provide for alternative verification requirements when a supplier is a farm that would not be subject to the requirements of proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm. Some of these farms would be not be subject to the requirements of proposed § 112.4 because they satisfy the criteria, in section 419(f) of the FD&C Act, for an exemption for direct farm marketing. Other farms would not be subject to the requirements of proposed § 112.4 because the crops they grow would not be covered by the proposed produce safety rule, either based on the findings of a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (see the discussion of this qualitative assessment of risk in the 2013 proposed produce safety rule, 78 FR 3504 at 3508 and 3522–3529) or because they account for a very small percentage of covered produce (see proposed § 112.4 and the discussion at 78 FR 3504 at 3549). Although the potential requirements would allow a receiving facility to conduct an alternative verification activity for such farms, they would not require this. Although the potential requirements would provide for alternative verification requirements for farms that would not be subject to the produce safety rule, we would not issue a final rule on such alternative verification requirements until we issue the final produce safety rule.

D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities

In the 2013 proposed FSVP rule, we tentatively concluded that it would be appropriate to address the independence of individuals conducting verification activities (78 FR 45730 at 45759). We proposed that an individual who conducts any verification activity must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity, and provided that this would not prohibit an importer, or the importer's employee, from conducting the verification activity (proposed § 1.506(g)). As discussed in the 2013 proposed FSVP rule, we considered such requirements necessary to prevent bias, or the appearance of bias, on the part of a person conducting a verification activity (78 FR 45730 at 45759).

We request comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements. For example, should such requirements be directed to a subset of persons who conduct verification activities (such as auditors) or should they be directed more broadly? Would a requirement such as in the 2013 proposed FSVP rule be appropriate, or would some other requirement be more appropriate (such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the activity)? What would constitute a financial interest in a company sufficient to constitute a conflict of interest for a person conducting a supplier verification activity (e.g., conducting an audit of that company or conducting laboratory tests of that company's food)?

XII. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration

A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration

In the 2013 proposed preventive controls rule, we announced our intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking rather than include them in the requirements for hazard analysis and

risk-based preventive controls (78 FR 3646 at 3659). We tentatively concluded 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 acknowledged 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. We provided an example of this kind of hazard—i.e., the addition of the chemical melamine to certain food products, apparently to enhance the measured protein content and/or perceived quality. We requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also requested comment on when an economically motivated adulterant can be considered reasonably likely to occur.

When we developed the 2013 proposed intentional contamination rule, we tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and for animal food (including hazard analysis, preventive controls, monitoring, corrective action, verification, and recordkeeping) rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism (see the 2013 proposed intentional adulteration rule, 78 FR 78014 at 7802). We also explained our view that the primary purpose of economically motivated adulteration is to obtain economic gain rather than to impact public health, although public health harm may occur (78 FR 78014 at 78020).

B. Comments on Economically Motivated Adulteration

Some comments oppose including requirements directed to economically motivated adulteration in the preventive controls rule. These comments assert that the vast majority of economically motivated adulterants affect quality and value rather than safety. These comments also point out that the majority of food products could, in theory, be subject to economically motivated adulteration but that it would be difficult to determine if such adulteration is reasonably foreseeable. One comment recommends that we draw a clear distinction between hazards that are intentionally introduced and those that are not. Another comment expresses the view that food fraud is fundamentally different from both food safety and food defense. However, some comments do support including ''expected intentional adulterants'' in the preventive controls rule and note that the U.S. Pharmacopeial Convention (USP) has a free on-line food fraud database (Ref. 25). (USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.)

C. Potential Requirements To Address Economically Motivated Adulteration

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on a potential requirement for the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain (see proposed § 117.130(b)(2)(iii) in proposed subpart C). In this section of this document, we are reopening the comment period with respect to our previous request for comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We are seeking comment on whether this preventive controls rule would be the most appropriate rule to address FSMA's requirements to address hazards that may be intentionally introduced (for purposes of economic gain) and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. We note that the preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 26) describes certain assumptions we are making about the preventive controls, and their implementation, that would be established and implemented by a facility that identifies a potential hazard that may be intentionally introduced for economic reasons as a significant hazard. We are seeking comment on alternative ways to control such hazards.

Under the definitions that would be established in the rule, a hazard would be an agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public health harm.

We believe that it is practicable to determine whether economically motivated adulteration is reasonably foreseeable. Importantly, we would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their food products. As discussed in the 2013 proposed intentional adulteration rule, we would expect facilities to focus on circumstances where there has been a pattern of such adulteration in the past, suggesting a potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product (78 FR 78014 at 78027). For example, in both the 2013 proposed preventive controls rule and the 2013 proposed intentional contamination rule we discussed a widespread incident of economically motivated adulteration in which some milk firms in one country added melamine, a nitrogen-rich industrial by-product, to diluted dairy products to increase the apparent protein content (78 FR 3646 at 3659 and 78 FR 78014 at 78021, respectively). This adulteration resulted in significant public health consequences, with more than 290,000 ill infants and 6 deaths in that country. In light of this incident, a prudent person would include in its hazard analysis the potential for melamine to be an economically motivated adulterant in a facility's food products when using milk products from a country where melamine adulteration had occurred and, based on the outcome of that hazard analysis, determine whether melamine is a hazard that must be addressed in the food safety plan. As none of this adulterated milk was exported to the United States and no US suppliers have been a source of food safety problems due to milk products adulterated for economic gain, FDA does not expect a facility to consider the potential for melamine to be a significant hazard when using domestic milk products, or milk products from other countries when there is no history of melamine adulteration associated with those countries.

There are other well-known substances that have been used in economically motivated adulteration schemes, have potential to cause public health harm, and would be prudent to consider in the types of food products that have been the subject of these schemes. For example, dyes containing the heavy metal lead have been added to ingredients such as spices to enhance color. Lead can accumulate in the body over time and can cause health problems, including such as impaired

cognitive development in children (Ref. 27). Lead chromate is a chemical with a vibrant yellow color that has been used as an adulterant in turmeric to change the color of the spice to suggest that it is of a higher quality (Ref. 28). Lead oxide is a red chemical that has been used as an adulterant in paprika to change the color of the spice to suggest that it is of a higher quality; in 1995, an incident was reported in Hungary in which dozens of people were made ill and several people died as a result of consuming contaminated paprika (Ref. 29). Sudan I is an orange-red powder that had been added to chili powder as a coloring agent, but is now banned in many countries because the International Agency for Research on Cancer has classified it as a category 3 carcinogen (not classifiable as to its carcinogenicity to humans) (Ref. 30); in 2005, contamination of an ingredient prepared using chili powder containing Sudan I led to a massive recall of food products in the United Kingdom (Ref. 31).

In addition to the food-fraud database mentioned in the comments, a recent report from the Congressional Research Service provides additional information on economically motivated adulteration of food and food ingredients (Ref. 32). A recent report identified 137 unique incidents in 11 food categories (Ref. 33).

XIII. Provisions for Withdrawal of an Exemption for a Qualified Facility

A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility

In the 2013 proposed preventive controls rule, we explained the provisions of FSMA that establish criteria for a facility to be a qualified facility, establish an exemption for qualified facilities, establish modified requirements for qualified facilities, and provide that we may withdraw the exemption otherwise granted to qualified facilities in specified circumstances (section 418(l) of the FD&C Act; see 78 FR 3646 at 3657). We proposed to establish:

Definitions relevant to these provisions (proposed § 117.3);

An exemption from the requirements for hazard analysis and risk-based preventive controls for qualified facilities (proposed § 117.5(a));

Modified requirements for qualified facilities (proposed § 117.201); and

Procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart E; the 2013 proposed withdrawal provisions) (see 78 FR 3702–3703, 3768–3771, and 3775–3780).

The 2013 proposed withdrawal provisions would:

Specify the circumstances under which we would withdraw an exemption for a qualified facility (proposed § 117.251);

Establish procedures for us to issue an order to withdraw the exemption, including information that would be in the order (proposed §§ 117.254 and 117.257);

Establish procedures whereby a qualified facility may submit a written appeal of our order to withdraw an exemption (proposed § 117.260 and 117.264);

Establish procedures for appeals, hearings, and decisions on appeals and hearings (proposed §§ 117.267, 117.270, 117.274, and 117.277); and

Specify the circumstances in which an order to withdraw an exemption is revoked (proposed § 117.280).

B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption

1. Comments

Some comments generally support the overall framework of the 2013 proposed withdrawal provisions and express the view that withdrawal of exemption should be both prompt and permanent to protect public health. Some comments ask us to explain the difference between withdrawal of an exemption and suspension of registration. One comment asks us to clarify the effect a suspension has on a qualified facility and recommends that suspension automatically result in loss of the exemption. One comment recommends that we withdraw an exemption at the earliest signs of problems, because doing so would be most protective of public health and would be consistent with the principle that a broad interpretation of statutory exemptions is disfavored when they affect public health and safety. This comment also asserts that section 418 of the FD&C Act provides a very low threshold for initiating a withdrawal action, makes that withdrawal permanent, and was designed to operate on a ''one strike, you're out'' principle. This comment asserts that the exemption section 418 provides to qualified facilities has no basis in food safety science or sound policy and endangers consumers and that withdrawal of an exemption would not result in overly harsh consequences because it would not close the facility. One comment discusses our authority to suspend the registration of a facility (section 102 of FSMA). This comment contrasts FSMA's provisions for withdrawal with those for suspension, noting that FSMA's provisions for suspension specify a method to lift that suspension (i.e., submission of a corrective action plan) but FSMA's provisions for withdrawal of an exemption provide no remedy for an exemption that is withdrawn.

In contrast, other comments express concern that the 2013 proposed withdrawal provisions fail to establish a fair and clear process for withdrawing a qualified facility's exempt status and recommend that we revise the 2013 proposed withdrawal provisions to provide a more flexible framework that would be both fair and clear. Some of these comments express concern that withdrawal of an exemption would subject very small and small facilities to unexpectedly high compliance costs that could put them out of business. Some comments recommend that we add a provision allowing a facility to voluntarily withdraw its exemption. Some comments recommend more safeguards to ensure that the process to withdraw an exemption is not abused. In general, these comments recommend the following three principal revisions to the 2013 proposed withdrawal provisions:

Establish a high threshold for withdrawing an exemption, including an evidentiary standard that would apply to the criteria for withdrawing an exemption;

Provide for ''due process'' before we take steps to withdraw an exemption, including an opportunity for a qualified facility to maintain its exempt status (e.g., by addressing the specified issues of concern); and

Provide an opportunity for reinstatement of a withdrawn exemption.

In the following paragraphs, we provide more detail about comments recommending these three principal revisions.

Threshold for withdrawing an exemption. Some comments assert that the 2013 proposed withdrawal provisions are extremely vague and appear to give us broad authority to withdraw an exemption from a qualified facility without adequate evidence of an actual harm or likely severe problem related to the facility's practices. Some comments assert that we should narrowly interpret the statutory criteria for withdrawing an exemption to avoid action that is arbitrary and capricious, and that to do so we must show necessity and direct linkage between an active investigation of a foodborne illness outbreak and the qualified facility. Some of these comments

recommend that we define and clarify key terms (including ''directly linked,'' ''necessary,'' ''associated,'' and ''material to the safety of food''). Some of these comments also recommend that we introduce a standard (such as ''credible evidence'' or ''credible and substantial evidence'' that shows direct linkage to a problem at a specific facility) that would require us to meet an explicit evidentiary threshold when we find that conduct or conditions exist in a qualified facility sufficient to warrant withdrawal of an exemption. Some comments recommend that the final withdrawal provisions explicitly provide that the credible and substantial evidence would only apply to an individual facility, and would not apply to a group or class of facilities.

Due process before withdrawing an exemption. Some comments note that we have many enforcement tools that we can use in lieu of withdrawing an exemption, particularly if there is an immediate risk to public health. These include seeking an injunction (21 U.S.C. 332; section 302 of the FD&C Act); seizing the food at issue (21 U.S.C. 334(a)–(f); section 304(a)–(f) of the FD&C Act); and administrative detention of the food (21 U.S.C. 334(h); section 304(h) of the FD&C Act). Other comments note that we have a history of providing a facility with opportunities to fix a problem before starting such an enforcement action (e.g., by issuing a warning letter). These comments recommend that we provide such opportunities to qualified facilities before we take steps to withdraw an exemption.

Some comments recommend that the final withdrawal provisions allow for partial withdrawal of an exemption in which FDA would indicate specific sections of the rule that the facility must comply with. These comments assert that small businesses should be able to seek targeted solutions as needed without falling under all the substantive, costly provisions of the rule. Some comments recommend that the final withdrawal provisions establish a three-tiered process—Tier 1: Warning letter; Tier 2: Temporary conditional withdrawal of an exemption; and Tier 3: Full withdrawal of an exemption. For example, a warning letter would identify the material conduct or conditions in question or how the facility is directly linked to an active investigation of a foodborne illness outbreak; include information about how the facility could remedy the situation; and notify the facility that it has 15 calendar days from receipt of the warning letter to respond with a plan for remedying the problem within a suitable timeframe. These comments state that if the facility does not adequately address the problem in its response to the warning letter and subsequent actions to correct the problem, we would issue a temporary (e.g., six months) conditional withdrawal, targeted to a particular issue, outlining how the facility can remedy the problem. These comments further state that if the facility still fails to correct the problem after receiving the temporary conditional withdrawal, we would proceed with steps for full withdrawal of an exemption.

Reinstatement of an exemption that was withdrawn. Some comments recommend that we provide a process for each of three situations in which a qualified facility might regain its exemption status:

Before reaching the deadline for compliance specified in the withdrawal order, if the facility demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved;

After the compliance deadline passes if, during an informal hearing, the facility can show that the conduct or conditions that triggered the withdrawal have been sufficiently resolved; or

Automatically if we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility.

2. Specific Proposed Additions and Modifications to the 2013 Proposed Withdrawal Provisions

As discussed more fully in the following paragraphs, taking into account the comments we have reviewed so far we are proposing to modify the 2013 proposed withdrawal provisions to:

Include specific regulatory actions that we must take, and other regulatory actions that we may consider, before we issue an order to withdraw an exemption (proposed § 117.251(b));

Clarify that an order to withdraw an exemption must be approved by an FDA District Director before it can be issued (proposed § 117.254(a) and (b)); and

Provide a process for reinstating an exemption that has been withdrawn (proposed § 117.287).

See the revised regulatory text for proposed §§ 117.251(b), 117.254(a) and (b), and 117.287. In this section of this document, we are reopening the comment period with respect to these specific proposed provisions.

Both of the proposed circumstances for withdrawal of an exemption specify significant public health reasons for doing so, related to an outbreak of foodborne illness, or being 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 (proposed §§ 117.251(a) and (b), respectively). We do not consider it necessary to define terms such as ''directly linked,'' ''necessary,'' ''associated,'' or ''material to the safety of food,'' or to introduce a standard (such as ''credible evidence'' or ''credible and substantial evidence'' that shows direct linkage to a problem on a specific farm or facility) to provide for a fair process that is neither arbitrary nor capricious.

We may suspend the registration of a facility if we determine that food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. If we suspend a facility's registration, no person can import or export food into the U.S. from such facility, offer to import or export food into the U.S. from such facility, or otherwise introduce food from such facility into intrastate or interstate commerce in the U.S. (See section 415(b) of the FD&C Act (21 U.S.C. 350d(b)). In contrast, we may withdraw an exemption from a qualified facility in two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or (2) if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. (See section 418(l)(3) of the FD&C Act). A facility that loses its exemption may distribute food if it is in compliance with applicable requirements.

The statutory criteria for suspension of registration are separate and distinct from the statutory criteria for withdrawal of an exemption and must be considered separately. Suspension of a facility's registration does not change a facility's status as a qualified facility. If we take steps to suspend a qualified facility's registration, we may also separately consider whether the circumstances that may lead us to withdraw the facility's exemption exist and, if so, may follow the process that would be established in the final withdrawal provisions for doing so.

As the comments point out, in many circumstances we have provided facilities with opportunities to fix a

problem before starting an enforcement action. Indeed, we consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions may provide a more expeditious approach to correcting a problem than withdrawing an exemption. However, taking into account the concerns expressed in the comments we have reviewed so far, we are proposing to include specific actions that we must take, and other actions that we may consider, before we issue an order to withdraw an exemption. (See the revised regulatory text for proposed § 117.251(b)). Briefly, the proposed regulatory text would provide that we:

Notify a qualified facility in writing of circumstances that may lead us to withdraw its exemption, and provide an opportunity for the facility to respond, before we issue an order to withdraw the exemption;

May consider alternative regulatory actions before issuing an order to withdraw an exemption; and

Consider actions taken by the facility to address the circumstances that may lead us to withdraw its exemption before issuing an order to withdraw the exemption.

We are not proposing that we always must take steps to withdraw an exemption at the earliest signs of problems. Not all problems would satisfy the statutory threshold for withdrawal of the exemption. Further, we believe it is appropriate to consider each situation on its individual merits, such as whether there are illnesses, whether there are significant violations that could have contributed to the problem, whether the facility has taken corrective actions to address the problem, and whether the actions taken are likely to prevent a reoccurrence of the situation. Moreover, FDA has other tools that may be available to more quickly protect public health, including recall and administrative detention.

Regarding reinstatement, we tentatively conclude that the absence of a specific provision in section 418 of the FD&C Act for the re-instatement of an exemption that is withdrawn does not preclude us from providing for such a process, by which a facility may regain its status as a qualified farm. The proposed regulatory text (see proposed § 117.287) would:

Provide that we could reinstate an exemption on our own initiative or in response to a written request from the facility;

Require that a written request from a facility include such data and information as are necessary to demonstrate that the facility has adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak;

Provide that if we had withdrawn the exemption due, in whole or in part, to an active investigation of a foodborne illness outbreak that had been directly linked to the qualified facility and later determine, after finishing the active investigation, that the outbreak was not directly linked to the facility, we would either;

Reinstate the exemption (if the only reason for the withdrawal had been the outbreak investigation); or

Inform the facility of our finding that the outbreak investigation was not directly linked to the facility, and provide an opportunity for the facility to request reinstatement (if the exemption was withdrawn, in part, due to conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility).

We are not proposing to provide for partial withdrawal of an exemption or establish the three-tiered process recommended in the comments (i.e., Warning letter; Temporary conditional withdrawal of an exemption; and Full withdrawal of an exemption). Such a process is not required by section 418 and would deprive FDA of needed flexibility to address the varying circumstances that might give rise to a possible withdrawal of the exemption. Further, the revised regulatory text provides for a qualified facility to receive written notification that circumstances may lead us to withdraw an exemption, and provides an opportunity for the facility to respond. FDA will consider this response and actions taken by the facility in determining whether to withdraw the exemption. In addition the newly proposed provision for reinstatement of an exemption provides an opportunity for a facility to return to its status as a qualified facility.

C. Proposed Revisions to the Content of an Order To Withdraw an Exemption

In this section of this document, we are reopening the comment period with respect to proposed § 117.257(d).

Some comments recommend that the order explicitly state that the facility has the option to either comply with the order or appeal the order (with a request for an informal hearing) within 10 calendar days.

We tentatively conclude that it would be useful for the order to itself specify the two options that a facility has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions). Therefore, we are proposing to revise the requirements for the contents of an order to explicitly mention these two options. See the revised regulatory text of proposed § 117.257(d).

D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order

In this section of this document, we are reopening the comment period with respect to the timeframes in proposed §§ 117.257(d) and 117.260(a) and (c).

1. Comments

Some comments ask us to specify that a facility's timeframe for taking action begins when the facility receives the order, not when we issue the order. Other comments address the timeframes for a facility to compile information needed to appeal an order for withdrawal. These comments assert that the proposed timeframe of 10 days is insufficient, and recommend timeframes such as 30 days or 90 days.

Some comments contrast the proposed 60-day timeframe to comply with the requirements for hazard analysis and risk-based preventive controls when a facility loses its exemption as a qualified facility with the timeframe that a facility would have to comply with these requirements when the final rule first becomes effective. As discussed in the 2013 proposed preventive controls rule, we proposed compliance dates that would be 2 years and 3 years after the date of the final rule for small and very small businesses, respectively. These comments assert that these two situations are parallel, because a qualified facility that has had its exemption withdrawn would be coming into compliance with the full requirements for hazard analysis and risk-based preventive controls for the first time. These comments recommend that we change the timeframes in the 2013 proposed withdrawal provisions to better align with the compliance dates contemplated by the proposed rule and by FSMA for small and very small businesses. Some of these comments recommend that a small business have 6 months, and that a very small business have 18 months, to comply with the order. Other comments recommend that any business (whether small or very small) have two years to comply with

the order. Some of these comments recommend that the timeframe be tied to the date of the final determination rather than to the date of the order.

2. Proposed Revisions to Timeframes

We tentatively conclude that the nature of what a facility would need to do to comply with an order—i.e., comply with the full requirements for hazard analysis and risk-based preventive controls—makes the timeframes in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the proposed withdrawal provisions would only apply when a significant public health concern has been identified for a particular facility.

We also tentatively conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (§ 1.402).

Taking into account the comments we have reviewed so far, we are proposing to require that a facility comply with an order to withdraw an exemption within 120 days of the date of receipt of the order. See the revised regulatory text for proposed §§ 117.257(d) and 117.260(a) and (c).

XIV. Definition of Very Small Business

A. The 2013 Proposed Options for Definition of Very Small Business

We proposed three options for the definition of a very small business based on total annual sales of food, adjusted for inflation: Option 1, $250,000; Option 2, $500,000; and Option 3, $1,000,000. The 2013 proposed preventive controls rule contained several provisions relevant to very small businesses, including exemptions from subpart C in § 117.5(g) and § 117.5(h) for very small (and small) facilities engaged only in specific types of on-farm activities involving low-risk activity/food combinations, the exemption in§ 117.5(a) and modified requirements in § 117.201 for a very small business as a qualified facility, and extended time to comply with the rule. In defining a very small business, we took into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act (''Food Processing Sector Study'' (Ref. 34); see 78 FR 3646 at 3700–3701). In the 2013 proposed preventive controls rule we requested comment regarding the three proposed options for the definition of ''very small business.'' We also requested comment on whether a dollar amount of sales that is more than, or less than, the $250,000, $500,000, or $1,000,000 amounts would be appropriate.

B. Comments on the 2013 Proposed Options for Definition of Very Small Business

Comments support a variety of dollar limits of total annual sales of food for defining a very small business, including each of the three proposed options ($250,000, $500,000, and $1,000,000) as well as other dollar limits that we did not include as proposed options (i.e., $2,000,000, $5,000,000 and $10,000,000). Comments assert that very small facilities will incur a large portion of the costs associated with implementing the 2013 proposed preventive controls rule because very small facilities lack experience with HACCP-based models.

Some comments support defining a very small business as one with total annual food sales up to $1,000,000. Some of these comments express concern that using lower dollar sales amounts to define a very small business would discourage growth of very small processing facilities (especially those co-located on a farm), would unfairly burden very small facilities, and could cause them to fail due to the estimated high cost of compliance; whereas setting a higher dollar sales amount would encourage growth, innovation and diversification. Some of these comments note that adopting the threshold of $1,000,000 would establish that the full preventive controls requirements would apply to the businesses that produce the vast majority of food products and that modified requirements would apply to smaller businesses that represent the majority of producers but the minority of the food supply.

Other comments support defining a very small business as one with total annual food sales up to $500,000. These comments maintain that the $500,000 limit would simplify the definition of a qualified facility, and make it easier for us to enforce than a lower dollar amount, because facilities would not need to calculate how much of their sales were to qualified end-users (as they would under section 418(l)(1)(C) of the FD&C Act).

Other comments support defining a very small business as one with total annual food sales up to $250,000. These comments maintain that the $250,000 limit would exempt the fewest facilities among the three proposed options and that this would be in the interest of public health. Comments assert that higher dollar limits would remove from the coverage of the 2013 proposed preventive controls rule precisely those companies whose practices would be most improved by it. Some of these comments evaluate the $250,000 limit in the context of section 418(l) of the FD&C Act, which defines a qualified facility as either a very small business or a business with annual sales of less than $500,000, provided a majority of its sales are made directly to qualified end-users. These comments note that the options with a limit higher than $250,000 would equal or exceed the amount allowed for sales by qualified facilities to nonqualified end users under section 418(l)(1)(C) of the FD&C Act and assert that statutory structure and intent of section 418(l) of the FD&C Act make the proposed $250,000 limit the only available option from among the three options we proposed. The comments also assert that the close producer-customer relationship was a control for safety when a business is smaller than $500,000 in sales and primarily sells directly to consumers or locally to food retailers and restaurants.

Some comments support defining a very small business as one with total annual food sales up to $2,000,000, $5,000,000 or $10,000,000. In general, these comments express concern about the costs associated with implementing the requirements for hazard analysis and risk-based preventive controls. For example, the comments assert that these costs would deter small farms with gross annual sales between $250,000 and $5 million from expanding their businesses (e.g., to develop value-added products), particularly when annual food sales include foods that would not be not covered by the requirements for hazard analysis and risk-based preventive controls (such as for animal food, whole produce, and low-risk activity/food combinations conducted by a small or very small business co-located on a farm), and the sales would largely be to qualified end-users. A comment recommending a $10,000,000 limit expresses concern that the costs associated with implementing the requirements for hazard analysis and risk-based preventive controls would be passed on to consumers.

Some comments do not support defining a very small business based on total annual food sales and recommend an alternative definition based on the number of employees (e.g., fewer than 20 employees). These comments assert that defining very small business based on number of employees would be consistent with the proposed definition of small business (which is based on number of employees) and with the smallest establishment size in the Food

Processing Sector Study. Other comments support using a combination of criteria for defining a very small business, including gross sales, number of employees and risk level of the food being prepared.

Some comments support using the volume of food rather than total annual food sales. Some comments express concern that the dollar sales would be applied to all food sold, including food for animals, and recommend that we base the value on food subject to the preventive controls for human food rule, on produce and processed food, on human food (excluding animal feed) or on ''high-risk processed foods.''

C. Proposed Revisions to the Definition of Very Small Business

In this supplemental notice of proposed rulemaking, we are proposing the definition of very small business as a business that has less than $1,000,000 in total annual sales of human food adjusted for inflation. This definition would, as recommended by some comments, simplify a facility's determination of whether it is a qualified facility because the facility would only need to calculate its total sales of human food rather than determine how much food was sold to qualified end-users. The statutory construct does not prevent us from establishing a definition for very small business that would include more facilities than those that would be included under the statutory provision that considers sales to qualified end-users (section 418(l)(1)(C) of the FD&C Act). Section 418(n)(1)(B) of the FD&C Act directs FDA to define the term ''very small business'' for the purposes of determining whether a facility is a ''qualified facility'' eligible for modified requirements. Further, section 418(n)(1)(B) requires us to consider the Food Processing Sector Study for the purpose of defining ''very small business.'' FDA notes that section 418 of the FD&C Act does not otherwise limit how FDA may define ''very small business.''

We tentatively conclude that it is reasonable for the sales limit in the definition of ''very small business'' to be directed to human food rather than all food, including animal food. The proposed definition of ''very small business'' in this document is consistent with the proposed definition of ''very small business'' in the 2013 proposed rule ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' (78 FR 64736, October 29, 2013), which would define such a business with respect to sales of animal food rather than all food. We do not expect that this proposed change would have a significant effect on the number of facilities that satisfy the definition of ''very small business,'' because most facilities subject to the statutory requirements for hazard analysis and risk-based preventive controls do not make both human and animal food. However, some facilities co-located on a farm that would not satisfy the definition of ''very small business'' if the limit on the sales of food includes animal food as well as human food may fall within the revised definition that would include a limit only on the sales of human food.

We tentatively conclude that it is not necessary for the dollar limit in the definition of ''very small business'' to be $250,000 or less to protect public health. In the 2013 proposed preventive controls rule, we estimated the number of facilities that would be affected by the size specified in the definition of ''very small business.'' The size specified in the definition of ''very small business'' would affect the compliance dates, the exemptions for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity food/combinations and on-farm low-risk manufacturing/processing activity food/combinations (proposed §§ 117.5(a), (g), and (h), respectively) (see 78 FR 3646 at 3702). We noted that 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. We acknowledge that this estimate of all food produced in the United States is higher than the estimates for lower dollar limits (one-half of one percent of all food produced in the United States, or less than one-half of one percent of all food produced in the United States, for limits of $500,000 or $250,000, respectively). Regardless, under the revised definition the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness.

In the proposed rule, we calculated the costs of the rule, and estimated the percent of food produced in the United States that would be subject to modified requirements (i.e., produced by qualified facilities), by determining which facilities would be qualified based on ''per facility'' sales. We believe our current calculation based on firm sales rather than facility sales is more consistent with section 418(l)(1)(B). In the updated PRIA (Ref. 26), we compare the numbers and their market share of qualified and non-qualified facilities under different definitions for a very small business using (1) the method in our original PRIA (the number of *facilities* with less than $1 million in annual sales) and (2) the number of *firms* with less than $1 million in annual sales (in which multiple facilities may be under the ownership of one firm). As noted in the updated PRIA (Ref. 26), in the final rule we will calculate the number of qualified facilities based on sales on a ''per firm'' basis. Calculating sales at the ''per firm'' level, we estimate that, as a group, those businesses that have less than $1,000,000 in total annual sales of foods produce less than one percent of the dollar value of food produced in the United States that would be covered by the rule without any special provisions for such businesses (Ref. 26), roughly equivalent to the percentage of food produced by very small businesses when the level for such entities is set at $250,000 if the ''per facility'' method of calculation is used. In contrast, higher dollar limits for very small business (such as the $2,000,000 or $5,000,000 limits recommended in some of the comments) using the ''per firm'' method would affect more of the food produced in the United States (approximately one percent and two percent, respectively, roughly equivalent to the levels of food affected when the level is set at $500,000 and $1,000,000, respectively, using the ''per facility'' method) (Ref. 26). We tentatively conclude that the definition of very small business should exempt from the rule only a small percent of food to minimize the risk of foodborne illness and, thus, are proposing a very small business definition of $1,000,000, which would exempt less than one percent of the dollar value of food produced in the United States. We request comment on this tentative conclusion and whether we should consider other dollar limits for very small business.

A dollar limit in the definition of ''very small business'' greater than $250,000 would not necessarily exempt those companies whose practices would be most improved by complying with the requirements for hazard analysis and risk-based preventive controls. The Food Processing Sector Study (Ref. 34) concluded that there was no consistent pattern across food categories in terms of which sizes of establishments contribute most to foodborne illness risk (78 FR 3646 at 3701). Moreover, the facilities that would be classified as qualified facilities would be subject to modified requirements (see proposed

§ 117.201). Furthermore, all facilities that would be exempt from the requirements for hazard analysis and risk-based preventive controls would continue to be subject to the prohibitions in the Federal Food, Drug, and Cosmetic Act against causing food to be adulterated or misbranded and against distributing such food and to inspection by FDA.

We are not proposing that the definition of ''very small business'' consider number of employees as well as dollar limits, be based on number of employees for consistency with the definition of ''small business,'' or be based on volume of food sold rather than on dollar limits associated with sales of food. There are two alternative sets of criteria to be a qualified facility. The criteria in section 418(l)(1)(C) of the FD&C Act are set out with regard to sales. We believe it is appropriate for the other criteria (related to being a ''very small business'') similarly to be related to sales. As discussed in the 2013 proposed preventive controls rule, we proposed number of employees for the definition of ''small business'' in part because it would be 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. We continue to believe that the proposed definition of ''small business,'' based on number of employees, is appropriate.

We are not proposing that the definition of ''very small business'' consider the risk associated with the food manufactured, processed, packed or held by the facility. The description ''very small'' addresses size of a business, not risk associated with food the facility manufactures, processes, packs, or holds.

XV. Other New and Revised Proposed Provisions

A. Proposed New Definitions

1. Proposed Definition of ''Pathogen''

In the 2013 proposed rule, we proposed to define ''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. Variations of the phrase ''microorganism of public health significance'' appear in several places in the existing CGMP regulations and in the 2013 proposed preventive controls rule. To both simplify the regulations and use the same term (i.e., ''pathogen'') when we mean a microorganism of public significance, we are proposing to define the term ''pathogen'' to mean a microorganism that is of public health significance and to replace variations of the phrase ''microorganism of public health significance'' with ''pathogen'' throughout the regulations.

2. Proposed Definition of ''You''

In the 2013 proposed preventive controls rule, we requested comment on whether there is any meaningful difference between the persons identified in current part 110 (i.e., ''plant management'' and ''operator'') and the ''owner, operator, or agent in charge'' identified in section 418 of the FD&C Act. We also requested 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 revised the proposed rule to use pronouns (such as ''you'' and ''your'') within proposed part 117.

Comments that responded to this request for comment focused on an approach that would make the regulations clear. However, the comments were divided in terms of how to best provide clarity, particularly with respect to use of pronouns such as ''you'' and ''your.'' Some of these comments express concern that it would be confusing if the phrase ''owner, operator, or agent in charge'' applied both to plant management and operators in the CGMP requirements (proposed subpart B, derived from current part 110) and to the ''owner, operator, or agent in charge of a facility'' in the requirements for hazard analysis and risk-based preventive controls (proposed subpart C). Other comments do not express this concern and note that the use of pronouns would, as we suggested, make the regulations more clear.

We acknowledge the potential for confusion if the phrase ''owner, operator, or agent in charge'' applies to both plant management and operators in proposed subpart B and to the ''owner, operator, or agent in charge of a facility'' in proposed subpart C. Most of the provisions of proposed subpart B do not specify the role of ''plant management'' or the ''operator'' of a plant or establishment. To prevent confusion, we tentatively conclude it is prudent to retain terms such as ''plant management'' and ''operator'' in proposed subpart B.

However, we tentatively conclude that we can simplify the regulations directed to the ''owner, operator, or agent in charge of a facility'' in provisions in subparts C, D, and E by using pronouns, without creating confusion, if we (1) define the term ''you'' to mean, for purposes of part 117, the owner, operator, or agent in charge of a facility and (2) limit use of the term ''you'' to provisions in proposed subparts C, D, and E. See the revised regulatory text for the definition of you (in proposed § 117.3) and its use throughout revised subpart C.

3. Proposed Definition of ''Significant Hazard''

As discussed in section IX.C, we are proposing to delete the proposed definition ''hazard reasonably likely to occur'' and instead establish a definition for ''significant hazard.'' See the revised regulatory text in proposed § 117.3.

4. Proposed Definition of ''Known or Reasonably Foreseeable Hazard''

As discussed in section IX.C, we are proposing to delete the proposed definition ''reasonably foreseeable hazard'' and instead establish a definition for ''known or reasonably foreseeable hazard.'' See the revised regulatory text in proposed § 117.3.

5. Potential Definitions of ''Qualified Auditor,'' ''Receiving Facility,'' and ''Supplier''

As discussed in section XI.C, we are providing an opportunity for public comment on potential requirements for a supplier program. If such requirements are included in a final rule, we would establish definitions for three terms used in the potential requirements for a supplier program—i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier.'' See the proposed regulatory text in proposed § 117.3.

B. Proposed Revisions to Definitions

In the 2013 proposed preventive controls rule, we proposed to:

Delete the definition of the term ''shall'' from the existing CGMP regulations;

Revise the definitions of several other terms in the existing CGMP regulations;

Retain the definitions of several other terms in the existing CGMP regulations, with no changes; and

Establish several new definitions.

We received comment on many of these proposed definitions. Taking into account the comments we have reviewed so far, we are proposing to revise the definitions for three of these terms.

1. Revised Definition of ''Cross-contact''

We proposed to define the term ''cross-contact'' to mean the unintentional incorporation of a food

allergen into a food. Some comments recommend that we define the term to be ''allergen cross-contact'' rather than ''cross-contact'' to reduce the potential for confusion with the term ''cross-contamination.'' We tentatively conclude that the term ''allergen cross-contact'' may reduce the potential for confusion with the term ''cross-contamination'' and are proposing to establish a definition for the term ''allergen cross-contact'' rather than the term ''cross-contact.''

2. Revised Definition of ''Hazard'' and ''Reasonably Foreseeable Hazard''

Some comments recommend that we include radiological hazards as a subset of chemical hazards in the definition ''hazard.'' Although radiological hazards would not be common, we believe that facilities in the past have considered them as chemical hazards when conducting a hazard analysis for the development of HACCP plans. The revised regulatory text uses the phrase ''chemical (including radiological)'' in the definition of ''hazard'' and as applicable throughout the regulations. As a conforming change, we are proposing to revise the definition of ''reasonably foreseeable hazard'' to mean a potential biological, chemical (including radiological), or physical hazard that may be associated with the facility or the food.

3. Revised Definition of Environmental Pathogen

We proposed 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. We identified *Salmonella* spp. and *Listeria monocytogenes* as examples of environmental pathogens. Some comments express concern that our proposed definition of ''environmental pathogen'' would capture organisms such as pathogenic sporeformers whose presence in and of itself would not constitute a risk to public health.

We are proposing to revise the definition of an environmental pathogen to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. The revised definition of ''environmental pathogen'' would specify that an environmental pathogen does not include the spores of pathogenic sporeformers and, thus, recognizes that consumption of food contaminated by the spores of a pathogenic sporeformer that is in the environment may not result in foodborne illness. For example, if food is contaminated with spores of *Clostridium botulinum,* the microorganism would not produce the botulinum toxin that causes illness unless these spores are subject to conditions that allow them to germinate into vegetative cells that produce the toxin. Pathogenic sporeformers are normally present in foods, and unless the foods are subjected to conditions that allow multiplication, they present minimal risk of causing illness.

C. Proposed Editorial Changes

The revised regulatory text includes several changes that we are making to make the requirements more clear and improve readability. We summarize the principal editorial changes in Table 8.

TABLE 8—PROPOSED EDITORIAL CHANGES

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout part 117	Substitute the term ''adequate'' for the term ''sufficient''.	For the purposes of part 117, there is no meaningful difference between ''adequate'' and ''sufficient.'' We proposed to retain the definition of ''adequate'' that is in the existing CGMP requirements in current part 110, but did not propose to define ''sufficient.'' We tentatively conclude that the regulations will be clearer if we use the single term ''adequate'' throughout the regulations.
Throughout subparts C, D, and E	Substitute the defined term ''you'' for ''owner, operator, or agent in charge of a facility''.	Improve clarity and readability.
117.126(c), 117.170(a)(4), 117.170(a)(5), 117.170(d).	Re-phrase the proposed requirements in active voice.	Improve clarity and readability.
117.126(d)	Specify that the food safety plan is a record that is subject to the requirements of subpart F within the requirements for the food safety plan (§ 117.126) rather than together with the requirements for other records required by the rule (§ 117.190).	Distinguish the requirements for the contents of the food safety plan from implementation records, which continue to be listed in § 117.190.
117.130(b)(1) and (b)(2)	Switch the order of paragraphs (b)(1) and (b)(2) compared to the order in the 2013 proposed preventive controls rule.	We tentatively conclude that it is more logical to specify what hazards must be considered (i.e., biological, chemical (including radiological), and physical) before specifying the reasons for how the hazards could get into the food products (i.e., naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain).
117.135	Shorten the title from ''Preventive controls for hazards that are reasonably likely to occur'' to ''Preventive Controls''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.

TABLE 8—PROPOSED EDITORIAL CHANGES—Continued

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
117.135(c)(1)	Rearrange the requirements for (1) parameters associated with the control of the hazard and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to be associated with process controls rather than be a standalone requirement.	It is more logical to place these requirements with process controls since their parameters and their values are associated with process controls.
117.135(c)(3) and 117.150(c)	Move requirements for corrections for sanitation controls from the requirements for preventive controls (proposed § 117.135) to the requirements for corrective actions (proposed § 117.150).	Improve clarity and readability.
117.137	Shorten the title from ''Recall plan for hazards that are reasonably likely to occur'' to ''Recall plan''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.
117.145, 117.150, 117.155	Redesignate the section numbers from the original section numbers in the 2013 proposed preventive controls rule (proposed §§ 117.140, 117.145, and 117.150, respectively).	Accommodate insertions of new § 117.136 (supplier program) and new § 117.140 (preventive control management components).
117.155, 117.160, 117.165, and 117.170.	Move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 117.150) to separate sections (proposed §§ 117.160, 117,165, and 117.170, respectively).	Improve clarity and readability.
117.170(a)(4)	Revise the requirements for reanalysis of the food safety plan after an unanticipated event in which a preventive control is not properly implemented to refer to the requirements for corrective actions in light of such an event rather than repeat the full text of those requirements for corrective actions.	Simplify the presentation of requirements and reduce redundancy in regulatory text for inter-related requirements.
117.170(c)	Specify the ''written food safety plan'' rather than the ''written plan.''.	Use the term ''food safety plan'' for consistency throughout subpart C.
117.170(c)	Specify ''document the basis for the conclusion that no revisions are needed'' rather than ''document the basis for the conclusion that no additional or revised preventive controls are needed''.	Improve clarity and readability.
117.170(e)	Specify ''You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding'' rather than ''FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.''	Improve clarity by specifying what the owner, operator, or agent in charge of the facility must do in certain circumstances rather than what FDA may require.
117.190	Change the title from ''Records required for subpart C'' to ''Implementation records''.	Accurately reflect the nature of the listed records after moving recordkeeping requirements for the food safety plan to § 117.126.
117.190(a)(3)(ii) and (iii)	Add ''verification of'' in front of ''monitoring'' and ''corrective actions''.	Distinguish these requirements for records applying to ''verification of monitoring'' and ''verification of corrective actions'' from other requirements for ''records of monitoring'' and ''records of corrective actions''.

XVI. Holding Human Food By-Products Intended for Use in Animal Food

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. Based on our interpretation of section 116, we proposed that subpart C would not apply with respect to alcoholic beverages at facilities meeting two specified conditions (proposed § 117.5(i); 78 FR 3646 at 3707 to 3709). We also proposed that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in the exemption, 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. However, we did note that in the case of a 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.

Some comments ask us to include the production of by-products of the alcoholic beverage manufacturing process (such as spent grains, distillers' grains, and grape pomace) within the exemption applicable to alcoholic beverages. These comments argue that the mere act of separating and disposing of those by-products by sale or otherwise should not trigger an

obligation to meet onerous and expensive food safety regulations.

The byproducts described in these comments appear to be products that would be used in food for animals rather than in human food. In response to the 2013 proposed animal food rule, we received many comments expressing concerns from brewers and distillers about whether that rule would allow them to continue providing spent grains for animal food. These spent grains are very commonly used as animal food, and are a subset of the much broader practice of human food manufacturers sending their peels, trimmings, and other by-products to local farmers or animal food manufacturers rather than to landfills.

Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed animal food rule. Human food processors already complying with human food safety requirements would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except for proposed CGMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., ensuring the by-product it is not comingled with garbage when being held or distributed). However, further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with the Preventive Controls for Animal Food rule. If any requirement regarding preventing physical and chemical contamination in human food by-products for use as animal food is finalized, it will be finalized as part of a final preventive controls rule for human food.

XVII. 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 PRIA that presents the benefits and costs of this proposed rule (Ref. 26). 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. 26) 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 (Public Law 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 $144 million, using the most current (2013) 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.

XVIII. 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.

Title: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule and Amendments to Proposed Rule

Description: FDA is proposing to amend its proposed regulation for Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food (CGMPs) to add requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act. The amendments include potential provisions that would require facilities to establish and implement, as necessary, the following verification activities: product testing, environmental monitoring, and a supplier program. In addition, FDA is amending its proposed rule to require that the hazard analysis and risk-based preventive controls for human food take into account the possibility of economically motivated adulteration of food.

Description of Respondents: Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act. Generally, a facility is required to register if it

manufactures, processes, packs, or holds food for consumption in the United States. There are 97,646 such facilities; 74,900 of which are considered ''qualified'' facilities under a very small business definition with a $1 million threshold and thus have reduced requirements in regards to this rule-making.

The information collection estimate for the preventive controls for human food proposed rule may increase if the potential requirements (the addition of provisions for product testing, environmental monitoring, a supplier program, and identifying any potential hazards caused because of economically motivated adulteration) are finalized. The information collection burden was previously estimated to be 3,686,897 hours; the revised estimate includes an additional 74,692 hours should the newly proposed provisions be finalized. To see the calculations for these additional burden hours, see Table 9. For more information on the original calculation of the information burden estimate please refer to the proposed rule PRA (See Ref. 194 in Docket FDA–2011–N–0920).

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

FDA estimates the burden for this information collection as follows:

Recordkeeping Burden

Should the potential provisions in this proposed rule be included in any final rule, we estimate 1,867 facilities subject to subpart C—Hazard Analysis and Risk-Based Preventive Controls will choose to include environmental monitoring procedures as a verification activity under § 117.165(a)(3). These facilities would need to write-up such procedures; a one-time burden of 16 hours (5.33 hours annualized). We also estimate that 319 food manufacturers would choose to make use of product testing as a verification activity under § 117.165(a)(2). These facilities would create written procedures for such testing. This is a one-time potential burden of 16 hours (5.33 hours annualized). These potential burdens are shown in Table 9 rows 1 and 2.

Should the potential supplier program discussed above be finalized a receiving facility would establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a hazard that needs to be addressed in the food safety plan; this includes whenever the receiving facility determines that a hazard that needs to be addressed in the food safety plan is controlled before receipt of the raw material or ingredient. We estimate that should this potential provision be included, about 2,417 receiving facilities would incur a one-time burden of 16 hours (5.33 hours annualized) to write up such a program. This potential burden is shown in Table 9 row 3.

Should product testing, environmental monitoring, and supplier programs be finalized, records would need to be reviewed and maintained. We estimate that there are 689 facilities that would review and keep such records as a result. These records would require on average about 30 minutes a month to review and file. There are operating and maintenance costs associated with the creation of these records in the form of product testing costs ($6,400,000 annually) and environmental monitoring sampling costs ($7,200,000 annually) and audits and ingredient testing costs of/for suppliers ($7,000,000 audits annually + $1,000,000 testing annually). This potential burden is shown in Table 9 row 4.

Under § 117.130(b)(2)(iii) the supplemental notice of proposed rulemaking adds a new element to the required hazard analysis to be performed by each facility. Facilities must now also consider hazards that may be intentionally introduced for purposes of economic gain. We estimate that this added requirement will increase the one-time needed to write up the hazard analysis by 1 to 5 hours (average 3 hours; 1 hour annualized burden over 3 years) depending on facility size and number of processes for 16,000 facilities. The operating and maintenance costs associated with conducting the initial hazard analysis to assess the possibility of EMA are $5,100,000. These estimates are shown in Table 9 row 5.

We estimate on an annual basis that all 16,000 facilities will spend 0.1 hours per year updating the EMA section of their hazard analyses and that this recurring burden has an associated operating and maintenance cost of $1,300,000. This burden is shown in Table 9 row 6.

Some receiving facilities will have supplying facilities that meet the definition of ''qualified'' facilities; these facilities are not required to comply with subpart C of the proposed rule. In addition, in some cases the supplier may be a farm not subject to the requirements in part 112 regarding the raw material or ingredient that the receiving facility receives from the farm. Under proposed § 117.136(c)(3) and § 117.136(c)(4) these qualified facilities and exempt farms will need to create written assurances (to be given to their receiving facility customers) to describe the processes and procedures that the supplier is following to ensure the safety of the food. We estimate that there are 14,212 facility suppliers and farms that would need to create these documents. We estimate that it will take 2 hours annually to prepare such documentation. This burden is shown in Table 9, row 7.

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN

21 CFR Part 117, subpart C	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping (in hours)	Total hours	Total operating and maintenance costs
Potential product testing written procedures (potential § 117.165(a)(2))	319	1	319	5.33	1,700	.....
Potential environmental monitoring written procedures (potential § 117.165(a)(3))	1,867	1	1,867	5.33	9,951	.....
Potential supplier program written (potential § 117.136(a)(2))	2,417	1	2,417	5.33	12,883	.....

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Part 117, subpart C	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping (in hours)	Total hours	Total operating and maintenance costs
§ 117.136(a)(3); § 117.165(a)(4) verification records	689	12	8,268	0.5	4,134	$21,600,000
§ 117.130(b)(2)(iii) written HA for EMA	16,000	1	16,000	1	16,000	$5,100,000
§ 117.130(b)(2)(iii) updating written HA for EMA	16,000	1	16,000	0.1	1,600	$1,300,000
§ 117.136(c)(3); § 117.136(c)(4) qualified or exempt suppliers assurances	14,212	1	14,212	2	28,424	
Total annual burden hours and costs					74,692	$28,000,000

Reporting Burden

There is no additional reporting burden under this supplemental notice of proposed rulemaking.

Third Party Disclosure Burden

There is no additional third party disclosure burden under this supplemental notice of proposed rulemaking.

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**.

XIX. 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 (Ref. 35) (Ref. 36). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XX. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments 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.*

XXI. 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. These references are also available electronically at *http://www.regulatons.gov.* We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

1. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day One. February 28, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm* and in Docket No. FDA–2011–N–0920.
2. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day Two. March 1, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm* and in Docket No. FDA–2011–N–0920.
3. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day One. March 11, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339097.htm* and in Docket No. FDA–2011–N–0920.
4. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day Two. March 12, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339097.htm* and in Docket No. FDA–2011–N–0920.
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11. FDA, ''Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide,'' 2012.
12. FDA, ''Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport,

Distribute, Receive, Hold, or Import Food (Edition 5),'' 2012.
13. FDA, ''What You Need to Know About Establishment and Maintenance of Records,'' 2014.
14. FDA, ''Guidance for Industry: Antimicrobial Food Additives,'' 1999.
15. Cooperative Extension Service, Division of Agricultural Sciences and Natural Resources, Oklahoma State University; USDA, Federal Grain Inspection Service; USDA, Extension Service; USDA, Animal and Plant Health Inspection Service, ''Stored Product Management,'' Circular No. E–912, January 1995. Available at *http://entomology.k-state.edu/doc/extension—crop-pests/E912_All_Stored_Product_May3.pdf.* Accessed and printed on August 14, 2014.
16. 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.
17. National Advisory Committee on Microbiological Criteria for Foods, ''Hazard Analysis and Critical Control Point Principles and Application Guidelines,'' Journal of Food Protection, 61:1246–1259, 1998.
18. FDA Memorandum, ''Product Testing,'' 2014.
19. Codex Alimentarius Commission, ''Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application. Annex to CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
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22. Codex Alimentarius Commission, ''Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, CAC/RCP 66–2008,'' 2008.
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35. FDA Memorandum, ''Re-proposal of select provisions of the Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,'' 2014.
36. FDA Memorandum, ''Modernization of food current Good Manufacturing Practices (cGMP) as required by the Food Safety Modernization Act of 2011,'' 2011.

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 117

Food packaging, Foods.

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, as proposed to be amended on January 16, 2013 (78 FR 3646), be further 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, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.227 is amended by revising the definitions for ''Farm'', ''Harvesting'', ''Holding'', and ''Packing'' to read as follows:

§ 1.227 What definitions apply to this subpart?

* * * * *

Farm means an establishment under one ownership 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 establishments that, in addition to these activities:

(1) Pack or hold raw agricultural commodities;

(2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and

(3) Manufacture/process food, provided that:

(i) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and

cooling raw agricultural commodities grown on a farm are examples of harvesting.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), 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.

* * * * *

■ 3. Section 1.328 is amended by revising the definitions for ''Farm'', ''Harvesting'', ''Holding'', and ''Packing'' to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

Farm means an establishment under one ownership 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 establishments that, in addition to these activities:

(1) Pack or hold raw agricultural commodities;

(2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and

(3) Manufacture/process food, provided that:

(i) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), 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.

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 4. 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.

■ 5. Section 16.1 is amended by revising the entry for ''§§ 117.251 through 117.284'' in paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 117.251 through 117.287 (part 117, subpart E), relating to withdrawal of an exemption applicable to a qualified facility.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 6. The authority citation for part 117, as proposed to be added on January 16, 2013 (78 FR 3646), continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 117.3 [Amended]

■ 7. Section 117.3 is amended as follows:

■ a. By removing the definitions for ''cross-contact'', ''hazard reasonably likely to occur'', and ''reasonably foreseeable hazard'';

■ b. By adding definitions for ''allergen-cross contact'', ''known or reasonably foreseeable hazard'', ''pathogen'', ''qualified auditor'', ''receiving facility'', ''significant hazard'', ''supplier'', and ''you ''; and

■ c. By revising the definitions for ''environmental pathogen'', ''harvesting'', ''hazard,'' ''holding'', ''packing'', and ''very small business''.

The additions and revisions read as follows:

§ 117.3 Definitions.

* * * * *

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

* * * * *

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), 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.

Pathogen means a microorganism of public health significance.

* * * * *

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 117.180(c)(2).

* * * * *

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

* * * * *

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of human food, adjusted for inflation.

* * * * *

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

■ 8. Amend § 117.5 by revising paragraph (k) to read as follows:

§ 117.5 Exemptions.

* * * * *

(k)(1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:

(i) ''Farms'' (as defined in § 1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this part in accordance with § 1.226(f);

(iii) 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;

(iv) Activities of ''farm mixed-type facilities'' (as defined in § 1.227) that fall within the definition of ''farm''; or

(v) Hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts).

(2) If a ''farm'' or ''farm mixed-type facility'' dries/dehydrates raw agricultural commodities to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B or with the applicable requirements for packing and holding in part 112 of this chapter.

■ 9. Revise subpart C to read as follows:

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

Sec.

§ 117.126 Food safety plan.

(a) Requirement for a food safety plan. (1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more qualified individuals.

(b) Contents of a food safety plan. The written 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 supplier program as required by § 117.136(a)(2);
(4) The written recall plan as required by § 117.137(a); and
(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);
(6) The written corrective action procedures as required by § 117.150(a)(1); and
(7) The written verification procedures as required by § 117.165(b).
(c) Records. The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 117.130 Hazard analysis.

(a) Requirement for a hazard analysis. (1) You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant hazards.
(2) The hazard analysis must be written.
(b) Hazard identification. The hazard identification must consider:
(1) Hazards that include:
(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
(iii) Physical hazards; and
(2) Hazards that may be present in the food for any of the following reasons:
(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.
(c) Hazard evaluation. (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.
(2) 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.

(a)(1) You must identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your 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.
(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and the food:
(i) Controls at critical control points (CCPs), if there are any CCPs; and
(ii) Controls, other than those at CCPs, that are also appropriate for food safety.
(b) Preventive controls must be written.
(c) Preventive controls include, as appropriate to the facility and the food:
(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the applicable control:
(i) Parameters associated with the control of the hazard; and
(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.
(2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:
(i) Ensuring protection of food from allergen 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. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:
(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
(ii) Prevention of allergen 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.
(4) Supplier controls. Supplier controls include the supplier program as required by § 117.136.
(5) Recall plan. Recall plan as required by § 117.137.
(6) Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 117.136 Supplier program.

(a) Supplier program. (1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.
(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:
(A) There are no significant hazards;
(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or
(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that

will significantly minimize or prevent the hazard.

(2) The supplier program must be written.

(3) The supplier program must include:

(i) Verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and

(ii) Verification activities and documentation of these activities, as required by paragraph (b) of this section, to verify that:

(A) The hazard is significantly minimized or prevented;

(B) The incoming raw material or ingredient 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: and

(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in a food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) Determination and documentation of the appropriate verification activities. In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;

(2) Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier's supplier;

(3) The supplier's procedures, processes, and practices related to the safety of the raw material and ingredients;

(4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food;

(5) The supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and

(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c) Supplier verification activities for raw materials and ingredients. (1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities as determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

(i) Onsite audits;

(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.

(iii) Review by the receiving facility of the supplier's relevant food safety records; or

(iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.

(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by § 117.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 117.3; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient 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. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d) Onsite audit. (1) An onsite audit of a supplier must be performed by a qualified auditor.

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. (1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

(2) For inspections conducted by the food safety authority of a country whose

food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to 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.

(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

(4) Documentation demonstrating that products are received only from approved suppliers;

(5) Documentation of an onsite audit. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

(6) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

(7) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and

(iii) Documentation that the review was conducted by a qualified individual.

(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.

(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;

(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:

(i) The documentation that the supplier is a qualified facility as defined by § 117.3; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient 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.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

§ 117.137 Recall plan.

For food with a significant hazard:

(a) You must establish a written recall plan for the food.

(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(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 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

(1) Monitoring in accordance with § 117.145;

(2) Corrective actions and corrections in accordance with § 117.150; and

(3) Verification in accordance with § 117.155.

(b) The supplier program established in § 117.136 is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program taking into account the nature of the hazard controlled before receipt of the raw material or ingredient:

(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 117.165(a)(4); and

(3) Reanalysis in accordance with § 117.170.

(c) The recall plan established in § 117.137 is not subject to the requirements of paragraph (a) of this section.

§ 117.145 Monitoring.

(a) As appropriate to the preventive control, you must:

(1) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) All monitoring of preventive controls in accordance with this section

must be documented in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

§ 117.150 Corrective actions and corrections.

(a) Corrective action procedures. As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(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 that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you 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 food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a specific corrective action procedure has not been established;

(ii) A preventive control is found to be ineffective; or

(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, 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 (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) Corrections applicable to food allergen controls and sanitation controls. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

(d) Documentation. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).

§ 117.155 Verification.

(a) Verification activities. Verification activities must include, as appropriate to the preventive control:

(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) Documentation. All verification activities conducted in accordance with this section must be documented in records.

§ 117.160 Validation.

(a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the significant hazards are adequate to do so as appropriate to the nature of the preventive control.

(b) The validation of the preventive controls:

(1) Must be performed (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 inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards; and

(3) Need not address:

(i) The food allergen controls in § 117.135(c)(2);

(ii) The sanitation controls in § 117.135(c)(3);

(iii) The supplier program in § 117.136; and

(iv) The recall plan in § 117.137.

§ 117.165 Verification of implementation and effectiveness.

(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control:

(1) Calibration of process monitoring instruments and verification instruments;

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

(4) 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 created.

(ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

(b) Written procedures. As appropriate to the facility, the food, and

the nature of the preventive control, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

§ 117.170 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan:

(1) At least once every 3 years;

(2) Whenever a significant change is made in the activities conducted at your facility if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(3) Whenever you become aware of new information about potential hazards associated with the food;

(4) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and

(5) Whenever you find that a preventive control is ineffective.

(b) You must complete the reanalysis required by paragraph (a) of this section 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.

(c) You must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed.

(d) A qualified individual must perform (or oversee) the reanalysis.

(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 117.180 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Review of records (§ 117.165(a)(4)); and

(4) Reanalysis of the food safety plan (§ 117.170(d)).

(b) A qualified auditor must conduct an onsite audit (§ 117.136(d)).

(c)(1) To be a qualified individual, the 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.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.190 Implementation records.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Records that document the monitoring of preventive controls;

(2) Records that document corrective actions;

(3) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(4) Records that document the supplier program; and

(5) Records that document applicable training for the qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

■ 10. Revise § 117.251 to read as follows:

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, import alert, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

■ 11. Revise § 117.254 to read as follows:

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) 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 before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(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.

■ 12. Amend § 117.257 by revising paragraph (d) to read as follows:

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

* * * * *

(d) A statement that the facility must either:

(1) Comply with subpart C of this part on the date that is 120 calendar days after the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

* * * * *

■ 13. Amend § 117.260 by revising paragraphs (a) and (c) to read as follows:

§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) If you receive an order under § 117.254 to withdraw an exemption applicable to that facility under § 117.5(a), you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

* * * * *

(c) If you appeal the order, and FDA confirms the order, you must comply with applicable requirements of this part within 120 calendar days of the date of receipt of confirmation of the order.

■ 14. Amend § 117.264 by revising paragraphs (a) introductory text and (a)(1) to read as follows:

§ 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), you 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 receipt of the order;

* * * * *

■ 15. Amend § 117.267 by revising paragraph (a) to read as follows:

§ 117.267 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of receipt of the order.

* * * * *

■ 16. Add § 117.287 to subpart E to read as follows:

§ 117.287 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your 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) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your 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) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your 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); and

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 117.251(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 117.5(a), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 117.251(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a) in accordance with the requirements of paragraph (b) of this section.

■ 17. Amend § 117.305 by revising paragraph (b) to read as follows:

§ 117.305 General requirements applying to records.

* * * * *

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

* * * * *

■ 18. Add § 117.330 to subpart F to read as follows:

§ 117.330 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

The proposed rule that is the subject of this document includes a discussion of our reconsideration of the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities (see the discussion of the proposed additional example of a harvesting activity in the definition of ''harvesting'' in section V.C and the discussion and Table 5 in section VII.C). Table 1 in this Appendix compares the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed preventive controls rule to our current thinking on the classification of these on-farm activities as a result of the proposed revisions to the ''farm'' definition. As can be seen in Table 1, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed preventive controls rule) that could be classified in more than one way.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES

Classification	Examples using the 2013 proposed ''farm'' definition *	Examples using the proposed revisions to the ''farm'' definition
Harvesting: Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting does not include activities that change a RAC into processed food.	• Cooling RACs. • *Fermenting cocoa beans and coffee beans*** (would change to ''holding''). • Filtering RACs. • Gathering RACs. • Removing stems and husks from RACs. • Shelling RACs. • Sifting RACs. • Threshing RACs. • Trimming of outer leaves from RACs. • Using pesticides in wash water on RACs. • Washing RACs.	• Cooling RACs. • *Field coring RACs* ** (new example, not previously classified). • Filtering RACs. • Gathering RACs. • Removing stems and husks from RACs. • Shelling RACs. • Sifting RACs. • Threshing RACs. • Trimming outer leaves from RACs. • Using pesticides in wash water on RACs. • Washing RACs.
Packing: Placing food in a container other than packaging the food and activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a RAC into a processed food.	• Coating RACs with wax/oil/resin for the purpose of storage or transport. • *Drying RACs for the purpose of storage or transport*** (would change to only be classified as ''holding''). • Labeling RACs. • Mixing RACs. • *Packaging a farm's or farm mixed-type facility's own RACs*** (would no longer be limited to ''own RACs''). • Putting RACs or individual unit cartons into non-consumer containers. • Sorting/grading/culling RACs. • Stickering RACs.	• Coating RACs with wax/oil/resin for the purpose of storage or transport. • *Cooling RACs*** (add'l classification) ***. • *Filtering RACs*** (add'l classification). • Labeling RACs. • Mixing RACs. • *Packaging RACs regardless of ownership*** (expanded to include others' RACs). • Putting RACs or individual unit cartons into non-consumer containers. • *Removing stems and husks from RACs*** (add'l classification). • *Sifting RACS*** (add'l classification). • Sorting/culling/grading RACs. • Stickering RACs. • *Using pesticides in wash water on RACs*** (add'l classification). • *Washing RACs*** (add'l classification).
Holding: Storage of food and activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, and activities performed as a practical necessity for the distribution of that food (such as blending of the same commodity and breaking down pallets)). Holding does not include activities that change a RAC into a processed food.	• Drying/dehydrating RACs during storage (incidental to *packing or* storing when the drying/dehydrating does not create a distinct commodity) ** (would no longer be incidental to packing, would only be incidental to holding). • Fumigating RACs during storage. • Sorting/culling/grading RACs. • Storing food.	• *Cooling RACs*** (add'l classification). • Drying/dehydrating RACs (incidental to storing when the drying/dehydrating does not create a distinct commodity). • *Fermenting cocoa beans and coffee beans* (change from previous classification as harvesting). • Fumigating RACs during storage to control pests. • Sorting/culling/grading RACs. • Storing food.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES—Continued

Classification	Examples using the 2013 proposed "farm" definition *	Examples using the proposed revisions to the "farm" definition
Manufacturing/Processing: 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.	• Artificial ripening. • Baking. • Boiling/Evaporating. • Bottling. • Canning. • Chopping. • Coating RACs for purposes other than storage/transport. • Cooking. • Cooling. • Coring. • Cracking. • Crushing. • Cutting. • Distilling. • Drying/dehydrating RACS to create a distinct commodity. • Eviscerating. • Extracting. • Formulating. • Freezing. • Grinding. • Homogenizing. • Infusing. • Irradiating. • Labeling (other than RACs). • Milling. • Mixing. • Packaging (other than RACs). • Pasteurizing. • Peeling. • Rendering. • Roasting. • Salting. • Slaughtering and post-slaughter operations. • Slicing. • Smoking. • Sorting, culling, grading (not incidental to packing or holding). • Trimming. • Washing. • Waxing.	• Artificial ripening. • Baking. • Boiling/Evaporating. • Bottling. • Canning. • Chopping. • Coating RACs for purposes other than storage/transport. • Cooking. • Cooling. • Coring (*except field coring*) ** (because field coring would be newly classified as harvesting). • Cracking. • Crushing. • Cutting. • Distilling. • Drying/dehydrating RACs to create a distinct commodity. • Eviscerating. • Extracting. • Formulating. • Freezing. • Grinding. • Homogenizing. • Infusing. • Irradiating. • Labeling (other than RACs). • Milling. • Mixing. • Packaging (other than RACs). • Pasteurizing. • Peeling. • Rendering. • Roasting. • Salting. • Slaughtering and post-slaughter operations. • Slicing. • Smoking. • Sorting, culling, grading (not incidental to packing or holding). • Trimming. • Washing. • Waxing.

* Examples were included in Table 4, Table 5, and/or Proposed §§ 117.3 and 117.5(g) and (h) in the 2013 Proposed Preventive Controls Rule and/or in the Draft Risk Assessment (Ref. 1).

** Activities listed in italics represent a change between the 2013 "farm" definition and our current thinking in light of the proposed revisions to the "farm" definition.

*** Add'l = additional.

The following reference has 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. This reference is also available electronically at *http://www.regulatons.gov.*

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.

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