Federal Register

4–18–07 Wednesday
Vol. 72 No. 74 Apr. 18, 2007

Pages 19375–19660

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

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.archives.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara,* available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via e-mail at *gpoaccess@gpo.gov.* The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 72 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**

General online information **202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

2. The relationship between the Federal Register and Code of Federal Regulations.

3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, May 8, 2007
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

Contents

Federal Register

Vol. 72, No. 74

Wednesday, April 18, 2007

Agriculture Department
See Forest Service
See Rural Business-Cooperative Service

Air Force Department
NOTICES
Environmental statements; record of decision:
Dyess Air Force Base, TX, and Barksdale Air Force Base, LA; Realistic Bomber Training Initiative, 19474

Army Department
NOTICES
Environmental statements; availability, etc.:
Base closures and realignments—
Fort Benning, GA, 19474–19475

Centers for Disease Control and Prevention
NOTICES
Meetings:
Disease, Disability, and Injury Prevention and Control Special Emphasis Panels, 19521–19522
National Center for Injury Prevention and Control Initial Review Group, 19522
Organization, functions, and authority delegations:
Coordinating Center for Infectious Diseases, 19522–19528

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration

Customs and Border Protection Bureau
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19548–19549

Defense Department
See Air Force Department
See Army Department
See Defense Logistics Agency
See Navy Department
PROPOSED RULES
Non-Federal entities authorized to operation on DoD installations; support standardization, 19411–19413
NOTICES
Meetings:
Care for America's Returning Wounded Warriors, President's Commission, 19470
Defense Acquisition University Board of Visitors, 19471
Privacy Act; systems of records, 19471–19473

Defense Logistics Agency
NOTICES
Environmental statements; availability, etc.:
National Defense Stockpile; removal of low-activity contamination, 19475

Denali Commission
NOTICES
Strategic plan; work plan (2007 FY), 19478–19485

Election Assistance Commission
NOTICES
Meetings; Sunshine Act, 19485

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Air pollutants, hazardous; national emission standards:
Startup, shutdown, and malfunction requirements; general provisions; reconsideration petition denied, 19385–19387
Air quality implementation plans; approval and promulgation; various States:
Utah; correction, 19383–19385
PROPOSED RULES
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
Indiana, 19413–19435
Ohio, 19435–19447
Pesticide programs:
Plant-incorporated protectorants; procedures and requirements—
Plant viral coat protein genes; Federal Insecticide, Fungicide, and Rodenticide Act tolerance exemption, 19590–19640
Plant virus coat proteins residues; Federal Food, Drug, and Cosmetic Act tolerance exemption, 19640–19660
NOTICES
Air pollution control:
State operating permits programs—
South Dakota, 19490–19491
Air programs:
State implementation plans; adequacy status for transportation conformity purposes—
Ohio, 19491
Pesticide registration, cancellation, etc.:
Pyridate, 19491–19493
Pesticides; experimental use permits, etc.:
BHN Research, 19494
Radiation protection programs:
Transuranic radioactive waste for disposal at Waste Isolation Pilot Plant; waste characterization program documents availability—
Los Alamos National Laboratory, NM, 19494–19499

Executive Office of the President
See Trade Representative, Office of United States

Federal Aviation Administration
RULES
Air carrier certification and operations:
National air tour safety standards
Information collection requirement approval, 19382–19383
Airworthiness directives:
Boeing, 19380–19382
NOTICES
Airport noise compatibility program:
Spirit of St. Louis Airport, MO, 19577–19578

Federal Communications Commission
RULES
Radio services, special:
Private land mobile radio services—
Spectrum efficient technologies; 150-174 and 421-512 MHz bands; schedule for transition to 6.25 kHz technology, etc., 19387–19390
Radio stations; table of assignments:
Kentucky, 19387
PROPOSED RULES
Radio stations; table of assignments:
Kansas, 19447–19448
Television broadcasting:
Video services provision in multiple dwelling units and other real estate developments; exclusive service contracts, 19448–19453
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19499–19502
Reports and guidance documents; availability, etc.:
Rehabilitation Act of 1973, Section 504 Handbook; policies and practices review, 19502–19503

Federal Deposit Insurance Corporation
RULES
Preserving Independence of Financial Institution Examinations Act of 2003; implementation:
Supplemental standards of ethical conduct for employees, 19375–19380

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation combined filings, 19487–19488
Hydroelectric applications, 19488–19489
Meetings:
High Island Offshore System, L.L.C.; settlement conference, 19489
Southwest Power Pool Board of Directors/Members Committee and SPP Regional State Committee, 19489–19490
Practice and procedure:
CDs, DVDs and other electronic media; submission guidelines, 19490
Applications, hearings, determinations, etc.:
Cheyenne Plains Gas Pipeline Co., L.L.C., 19485–19486
Enstor Gulf Coast Storage, LLC, 19486–19487
Erie Boulevard Hydropower, L.P., 19487

Federal Highway Administration
NOTICES
Highway planning and construction; licenses, permits, approvals, etc.:
Roanoke, Franklin and Henry Counties, VA, 19578–19579

Federal Maritime Commission
NOTICES
Agreements filed, etc., 19503–19504
Ocean transportation intermediary licenses:
Carex Shipping, LLC, et al., 19504
Clarion Logistics USA, Inc., et al., 19504
Daily Freight Cargo, Corp., et al., 19504–19505

Federal Mine Safety and Health Review Commission
NOTICES
Meetings; Sunshine Act, 19552

Federal Railroad Administration
NOTICES
Exemption petitions:
Union Pacific Railroad Co., 19579

Federal Reserve System
NOTICES
Banks and bank holding companies:
Change in bank control, 19505
Formations, acquisitions, and mergers, 19505
Meetings; Sunshine Act, 19505

Federal Trade Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19505–19511

Fish and Wildlife Service
NOTICES
Endangered and threatened species:
Canada lynx, etc.; 5-year review, 19549–19551

Food and Drug Administration
NOTICES
Meetings:
Medical Device User Fee and Modernization Act of 2002, 19528–19534
Memorandums of understanding:
National Cancer Institute; electronic exchange and analysis of data from research studies on investigational drugs; standards-based data repository creation, 19534–19539

Forest Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19461
Meetings:
National Urban and Community Forestry Advisory Council, 19461–19462

Health and Human Services Department
See Centers for Disease Control and Prevention
See Food and Drug Administration
See Health Resources and Services Administration
See National Institutes of Health
NOTICES
Grants and cooperative agreements; availability, etc.:
Healthy People 2010 targets; advancing system improvements, 19512–19521
Meetings:
Blood Safety and Availability Advisory Committee, 19521

Health Resources and Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19540
Organization, functions, and authority delegations:
Clinician Recruitment and Service Bureau, 19540–19541
Financial Management Office et al., 19541–19544

Homeland Security Department
See Customs and Border Protection Bureau

Interior Department
See Fish and Wildlife Service

International Trade Administration
NOTICES
Meetings:
President's Export Council, 19468
North American Free Trade Agreement (NAFTA); panel reviews:
Copper pipe fittings from—
United States, 19468–19469

Labor Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19551–19552

Mine Safety and Health Federal Review Commission
See Federal Mine Safety and Health Review Commission

National Institutes of Health
NOTICES
Meetings:
Director's Council of Public Representatives, 19544
National Center on Minority Health and Health Disparities, 19544
National Institute of Allergy and Infectious Diseases, 19546–19547
National Institute of Child Health and Human Development, 19545
National Institute of Dental and Craniofacial Research, 19546–19547
National Institute of Diabetes and Digestive and Kidney Diseases, 19545–19546
National Institute on Aging, 19545
National Institute on Alcohol Abuse and Alcoholism, 19544
National Institute on Drug Abuse, 19545
National Library of Medicine, 19547–19548
Scientific Review Center, 19548

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
West Coast States and Western Pacific fisheries—
Pacific Coast groundfish, 19390–19410
PROPOSED RULES
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Bering Sea and Aleutian Islands salmon, 19454–19460
West Coast States and Western Pacific fisheries—
Highly migratory species; vessel identification requirements, 19453–19454
NOTICES
Endangered and threatened species permit applications, determinations, etc., 19469
Marine mammal permit applications, determinations, etc., 19469–19470
Meetings:
Pacific Fishery Management Council, 19470

Navy Department
NOTICES
Privacy Act; systems of records, 19475–19478

Nuclear Regulatory Commission
NOTICES
Meetings:
Reactor Safeguards Advisory Committee, 19552–19553
Reports and guidance documents; availability, etc.:
Preclosure safety analysis; information and reliability estimation; correction, 19553–19554

Office of United States Trade Representative
See Trade Representative, Office of United States

Overseas Private Investment Corporation
NOTICES
Meetings; Sunshine Act, 19555

Pipeline and Hazardous Materials Safety Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19579–19580

Railroad Retirement Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19555–19556

Rural Business-Cooperative Service
NOTICES
Grants and cooperative agreements; availability, etc.:
Rural Cooperative Development Program, 19462–19468

Securities and Exchange Commission
NOTICES
Joint industry plan:
Chicago Board Options Exchange, Inc., et al., 19556–19560
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 19560–19561
Fixed Income Clearing Corp., 19561–19562
NASDAQ Stock Market LLC, 19562–19570
New York Stock Exchange LLC, 19570–19571
NYSE Arca, Inc., 19571–19577

Small Business Administration
NOTICES
Meetings:
Regulatory Fairness Board—
Region I; hearing, 19577

Thrift Supervision Office
NOTICES
Privacy Act; systems of records, 19580–19585

Trade Representative, Office of United States
NOTICES
World Trade Organization:
Dispute settlement panel proceedings—
India; additional and extra additional duties on imports, 19554–19555

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Railroad Administration
See Pipeline and Hazardous Materials Safety Administration

Treasury Department
See Thrift Supervision Office

Veterans Affairs Department
RULES
Vocational rehabilitation and education:
Montgomery GI Bill-Active Duty entitlement; transfer to dependents option; correction, 19383
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 19585–19588

Separate Parts In This Issue

Part II
Environmental Protection Agency, 19590–19660

Reader Aids

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

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

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

5 CFR
3201 19375

14 CFR
39 19380
91 19382
136 19382

32 CFR
Proposed Rules:
213 19411

38 CFR
21 19383

40 CFR
52 19383
63 19385
65 19385
Proposed Rules:
52 (3 documents) 19413, 19424, 19435
81 (3 documents) 19413, 19424, 19435
174 (2 documents) 19590, 19640

47 CFR
73 19387
90 19387
Proposed Rules:
73 19447
76 19448

50 CFR
660 19390
Proposed Rules:
660 19453
679 19454

Rules and Regulations

Federal Register
Vol. 72, No. 74
Wednesday, April 18, 2007

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

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

FEDERAL DEPOSIT INSURANCE CORPORATION

5 CFR Part 3201

RIN 3209–AA15

Supplemental Standards of Ethical Conduct for FDIC Employees

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The FDIC is finalizing the proposed rule to amend existing FDIC ethics regulations involving extensions of credit, ownership of stock, and definitions. It implements the Preserving Independence of Financial Institution Examinations Act of 2003, which amended sections 212 and 213 of title 18 of the United States Code. These sections continue generally to impose criminal penalties on examiners' borrowing from banks they have examined, and financial institutions' extending a loan to anyone who examines or has authority to examine that institution. The statutory amendment, however, decriminalizes extensions of credit to examiners for credit cards and for primary residential home loans from institutions that they examine or have authority to examine if these loans are made on the same terms and conditions as are available to other cardholders and borrowers and satisfy other criteria contained in the statute as amended. Additionally, the final rule clarifies and makes minor revisions to definitions and restrictions for FDIC employees' acquisition, ownership, or control of securities of FDIC-insured depository institutions and certain holding companies.

DATES: The final rule is effective May 18, 2007.

FOR FURTHER INFORMATION CONTACT: *FDIC:* Robert J. Fagan, Ethics Program Manager, Legal Division, (202) 898–6808; and Michelle Borzillo, Counsel, Legal Division, (202) 898–7400.

SUPPLEMENTARY INFORMATION:

I. Background

On December 4, 2006, the FDIC published a notice of proposed rulemaking to amend 5 CFR part 3201, entitled ''Supplemental Standards of Ethical Conduct for FDIC Employees.'' The FDIC is adopting the proposed rule as final. It addresses issues involving extensions of credit to all FDIC employees, including FDIC employees covered by the amended criminal statutes pertaining to examiners, members of the FDIC Board of Directors, Division and Office Directors, and their direct subordinates, as well as employees in the Corporate Employee Program who perform examiner functions (''covered employees''). This final rule also clarifies and makes minor revisions to the provisions governing employee ownership of stock and the definitions used in the regulation.

On December 19, 2003, the President signed Public Law 108–198, the Preserving Independence of Financial Institution Examinations Act of 2003. The bill amended sections 212 and 213 of title 18 of the United States Code. These sections continue generally to impose criminal penalties on examiners' borrowing from banks they examine, and financial institutions' extending a loan to anyone who examines or has authority to examine that institution. The amendment, however, decriminalizes extensions of credit to examiners for credit cards and for primary residential home loans from institutions that they examine or have authority to examine if these loans are made on the same terms and conditions as are available to other cardholders and borrowers.

The amended statute at 18 U.S.C. 212 provides that, subject to the exception noted above, any officer, director, or employee of a financial institution, who makes or grants any loan or gratuity, to any examiner or assistant examiner who examines or has authority to examine such bank, branch, agency, organization, corporation, association, or institution is subject to criminal penalties.

Under 18 U.S.C. 213, as amended, any examiner or assistant examiner who accepts a loan or gratuity, except for primary residential loans or credit cards described in this final rule, from any bank, branch, agency, organization, corporation, association, or institution examined by the examiner or from any person connected with it, is subject to criminal penalties and will be disqualified from holding office as an examiner.

On April 7, 2004, based on the statutory amendments, FDIC's Board of Directors adopted the Interim Policy on Credit Cards and Home Mortgages (''Interim Policy'') pending revisions to the FDIC's existing regulation on extensions of credit. The Interim Policy permits extensions of credit in the form of home mortgages for primary residences and credit cards under certain conditions. This final rule replaces the Interim Policy and supersedes the current version of 5 CFR 3201.102.[1]

Additionally, the final rule clarifies and makes revisions to 5 CFR 3201.103, which restricts FDIC employees' acquisition, ownership, or control of securities of FDIC-insured depository institutions and certain holding companies. Finally, the final rule makes appropriate revisions to the definitions in 5 CFR 3201.101.

In making these regulatory revisions in part pursuant to its rulemaking authority under 18 U.S.C. 212(b), the FDIC has consulted with the other Federal financial institution regulatory agencies. In addition, the FDIC has determined, with Office of Government Ethics (OGE) concurrence, that, under 5 CFR 2635.403(a) of the executive branch standards of ethical conduct, these

[1] Under the regulation, before being modified by the Interim Policy adopted by the FDIC Board of Directors in April 2004, the staff responsible for examination of FDIC-insured depository institutions were prohibited from obtaining credit from an FDIC-insured State nonmember bank, any subsidiary of such bank, or any person associated with such bank. No exceptions were made for home mortgages. An exception was made for credit cards issued outside the region or field office of assignment. Corporation officials in top management positions were prohibited under the regulation from entering into financial obligations with an institution over which the Corporation had primary Federal supervisory authority and its subsidiaries. An employee in the Division of Finance, Division of Insurance and Research, Division of Resolutions and Receiverships, the Legal Division, or who was a member of a standing committee of the Board of Directors, was prohibited from obtaining credit from an FDIC-insured depository institution or its subsidiary for a period of two years after the employee had participated personally and substantially in certain matters affecting the institution, its predecessor, successor, or affiliate. An exception was made for ordinary credit cards.

revised provisions as to FDIC employees, their spouses and minor children, are needed so that a reasonable person would not question the impartiality and objectivity with which agency programs are administered. Further, with respect to the revised restrictions and prohibitions on the holding of financial interests (including indebtedness, *i.e.*, certain extensions of credit and loans) by the spouses and minor children of FDIC employees and covered FDIC employees, the FDIC has determined that there is a direct and appropriate nexus between such restrictions and prohibitions as applied to spouses and minor children and the efficiency of the service.

II. Comments on the Proposed Rule

The FDIC received one comment on the proposed rule. The commenter addressed only the use of plain language and did not comment on the substance of the rule. The commenter offered several plain language suggestions which the commenter believes would make the rule easier to read and understand.

The FDIC has considered these comments and opted to finalize the rule as proposed without change for the following reasons. The rule restates and codifies the FDIC's longstanding interim policy that was well-known and understood by FDIC employees and the FDIC's ethics officials. The rule applies only to FDIC employees—it does not apply to non-FDIC employees and therefore has no impact on the public. Additionally, OGE concurred in the proposed rule prior to its publication as required by 5 CFR 2635.105 entitled ''Supplemental Agency Regulations'', and is also concurring in the final rule.

The commenter found it confusing that the proposed rule used two different terms to refer to FDIC employees: ''covered employees'' and ''FDIC employees.'' This use of two different terms is intentional. The term ''covered employee'' is defined in § 3201.101(d)(3) and includes employees occupying certain identified positions within the FDIC, while other provisions of the rule apply to all ''FDIC employees.'' The regulation uses the different terms to distinguish between the provisions that apply only to ''covered employees'' from the provisions that apply to all ''FDIC employees.''

For example, the final rule restates the general rule that all ''FDIC employees'' are prohibited from participating in an examination, audit, visitation, review, or investigation, or any other particular matter involving an FDIC-insured institution, subsidiary or other person with whom that employee has an outstanding extension of credit. ''Covered employees'' under the final rule may obtain a waiver from that general prohibition under the conditions and circumstances specified in the final rule. ''Covered employees'' are more restricted than all ''FDIC employees.''

III. The Final Rule

Section 3201.102—Extensions of Credit and Loans From FDIC-Insured Institutions

The revision to 5 CFR 3201.102 retains the existing general prohibitions on borrowings and disqualification provisions for FDIC employees and members of the FDIC Board of Directors. Likewise, a current or contingent financial obligation of an employee's spouse or minor child is considered to be an obligation of the employee. However, the final rule in a new paragraph (e) authorizes the FDIC Ethics Counselor to waive any disqualification under this section based on a determination with the advice of the Legal Division that the waiver is not inconsistent with the standards of ethical conduct for employees of the executive branch as set forth in 5 CFR part 2635 or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality and objectivity with which the FDIC programs are administered.

The final rule, in keeping with the amended statutes at 18 U.S.C. 212 and 213, eliminates the current regulatory disqualification for FDIC examiners, FDIC Board members, Division and Office Directors, and their immediate subordinates, and employees in the Corporate Employee Program performing examiner duties (defined as ''covered employees'' in § 3201.101(d)(3) of the rule), who obtain credit cards on terms and conditions no more favorable than generally available to other borrowers. See new paragraphs (c)(1) and (c)(2) of § 3201.102. Covered employees assigned to a bank from which they hold a credit card must inform their supervisor and ethics official prior to the examination or other participation in a matter involving the bank if any issue exists such as non-current payments, a billing dispute, or if negotiating with the bank concerning the debt. In certain cases, a disqualification will be required. Under paragraph (d)(4) of § 3201.102, covered employees and their spouses and minor children are prohibited from applying for or receiving a credit card from an institution if the covered employee is assigned or about to be assigned to an examination of that institution.

Under § 3201.102(c)(3)(ii), disqualification will continue to be generally required for residential real property loans on a primary residence. However, such loans are permitted in accordance with paragraph (c)(2)(ii) of § 3201.102, if the terms and conditions are no more favorable than the terms and conditions of loans generally available to other similarly situated creditworthy borrowers. Thus, covered FDIC employees can obtain such permitted loans, but will need to be recused from official participation in any particular matters involving the lending institution or person. The final rule also covers limitations, restrictions, and the mechanism for waiver of the disqualification from participation in an examination or other matter in appropriate circumstances, under paragraphs (c)(4), (c)(5), (d) and (e) of § 3201.102, as amended.

As previously noted above, a new general waiver will be available under the final rule in certain circumstances. Specifically, paragraph (e) of § 3201.102 authorizes the Ethics Counselor to waive any provision based on a determination with the advice of the Legal Division that the waiver is not inconsistent with the standards of ethical conduct for employees of the executive branch as set forth in 5 CFR part 2635 or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality and objectivity with which the FDIC programs are administered. A waiver under paragraph (e) of § 3201.102 could impose appropriate conditions, such as requiring the execution of a written disqualification.

Under paragraph (c)(5)(i) of § 3201.102, a covered FDIC employee is not prohibited from retaining a loan or extension of credit from a State nonmember bank or its subsidiary on its original terms if it was obtained prior to FDIC employment or reassignment to a covered employee position, or a result of the sale, or transfer of the loan or credit extension to, or the conversion or merger of the lender into, such a bank (or subsidiary). However, any renewal or renegotiation of such a pre-existing loan or credit extension is subject to the prohibitions in paragraphs (c)(3) and (c)(4) of § 3201.102, subject to an exception noted in the following sentence. Under paragraph (c)(5)(ii) of

§ 3201.102, a covered employee who experiences financial or other hardship unless allowed to renegotiate credit incurred prior to FDIC employment or reassignment of duties could submit a request for a waiver to his or her supervisor and the Ethics Counselor setting forth the reasons for the desired renegotiation and other details. After consideration, the employee's supervisor and the Ethics Counselor could jointly grant a written waiver of the prohibition based on a finding that the renegotiation would not be prohibited by law and that the waiver would not result in a loss of impartiality or objectivity or misuse of the employee's position.

Paragraph (d) of § 3201.102 of the final rule also prohibits an FDIC employee (other than examiners who are covered by the statutory prohibition under 18 U.S.C. 212 and 213) from directly or indirectly accepting or becoming obligated on any extension of credit from an FDIC-insured depository institution or its subsidiary for a period of two years from the date of the employee's last personal and substantial participation in an audit, resolution, liquidation, assistance transaction, supervisory proceeding, or internal agency deliberation affecting that particular institution, its predecessor or successor, or any subsidiary of such institution. This prohibition does not apply to credit obtained through the use of a credit card or a residential real property loan secured by the principal residence of the employee, subject to the same conditions, limitations, disqualification, and waiver procedures applicable to covered employees under paragraphs (c) and (e) of § 3201.102.

Section 3201.103—Prohibition on Acquisition, Ownership or Control of Securities of FDIC-Insured Depository Institutions and Certain Holding Companies

In addition, this final rule amends 5 CFR 3201.103, which generally provides in paragraph (a), with certain exceptions set forth in paragraph (b), that no FDIC employee, spouse of an employee, or minor child of an employee may acquire, own, or control, directly or indirectly, a security of an FDIC-insured depository institution or its affiliate. The existing regulation at 5 CFR 3201.103(b) provides six exceptions to that general prohibition: (1) Acquiring, owning, or controlling securities of certain bank holding companies or their nonbank subsidiaries that are publicly traded, not primarily engaged in banking, and exempt from the Bank Holding Company Act; (2) acquiring, owning, or controlling securities of certain nonfinancial savings association holding companies; (3) retaining securities of an FDIC-insured depository institution or affiliate if retention was permitted under 12 CFR part 336 prior to a certain date, prior to employment with the FDIC, or when the securities were acquired by a spouse prior to his or her marriage to the employee; (4) acquiring, owning, or controlling securities of an FDIC-insured depository institution or affiliate if acquired by inheritance, gift, stock split, involuntary stock dividend, merger, acquisition, or other change in corporate ownership, exercise of preemptive right, or otherwise without specific intent to acquire it, or if acquired by a spouse or minor child as part of a compensation package from their employer, subject to certain disclosure and disqualification requirements; (5) acquiring, owning, or controlling an interest in certain publicly traded or publicly available investment funds; and (6) using an FDIC-insured depository institution or affiliate as a custodian or trustee of accounts containing tax-deferred retirement funds. The final rule narrows the scope of these prohibitions and generally clarifies the prohibitions of this section.

Revised § 3201.103(a) as revised narrows the scope of the general prohibition concerning ownership and control of a security by FDIC employees, spouses and their minor children by removing the prohibitions on ownership of securities with respect to insured depository institution affiliates, other than certain holding companies. The reason for eliminating other affiliates from the prohibition is that the potential for a conflict of interest is generally only present when there is ownership or control of a company that in turn has control of an insured depository institution. Affiliates other than holding companies do not own, and generally do not control, an insured depository institution that is their parent or sister organization.

Section 3201.103 as revised generally prohibits ownership of a security of, in addition to an FDIC-insured bank or savings association; a bank holding company that is subject to supervision by the Federal Reserve Board (FRB); a savings and loan holding company that is subject to supervision by the Office of Thrift Supervision (OTS); a financial holding company that is subject to supervision by the FRB; and a company that (i) owns or controls an FDIC-insured bank or savings association, (ii) is not an FRB-supervised bank holding company, an OTS-supervised savings and loan holding company, nor an FRB-supervised financial holding company, and (iii) either is primarily engaged in banking or is not publicly traded on a U.S. securities exchange. These categories, in appropriate cases, cover companies that control industrial banks.

Section 3201.103 as revised also creates in paragraph (b)(1), a specific exception for acquisition, ownership, or control of securities of a unitary thrift holding company. In addition, the final rule reorganizes the descriptions of the prohibited securities and exceptions. The intent of the reorganization is to make this section clearer and more useable. The final rule retains in revised paragraphs (b) and (c) the other existing exceptions, limitations, and divestiture requirements of § 3201.103. Moreover, in a new paragraph (d) of this section, the final rule adds a provision for written waiver in appropriate circumstances by the Ethics Counselor, with Legal Division advice and legal clearance, of any provision of the section that is identical to the § 3201.102(e) waiver provision discussed above.

Section 3201.101(d)—General Section; Definitions

Finally, the definitional section at paragraph (d) of § 3201.101 is amended to add and revise certain useful definitions and delete others (''assisted entity'' and ''assuming entity'') that are no longer used.

The term ''covered employees'' is expanded to include employees whose duties and responsibilities include the examination of a financial institution or participation in the examination of any financial institution. The FDIC is republishing all the definitions in the paragraph, including those not being revised, for ease of reference.

Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) requires that each Federal agency either certify that a final rule would not have a significant impact on a substantial number of small entities. See 5 U.S.C. 603, 605. The Small Business Administration (SBA) defines small banks as those with less than $165 million in assets. The final rule implements the statutory decriminalization under certain circumstances of extensions of credit to FDIC examiners for credit cards and for primary residential home loans from institutions that they examine and clarifies certain restrictions on the acquisition, ownership, or control of securities of FDIC-insured depository institutions and certain holding companies on the part of FDIC employees. The final rule does not impose any obligations or restrictions

on depository institutions, including small depository institutions. On this basis, the FDIC certifies pursuant to 5 U.S.C. 605(b) that this final rule will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

The FDIC has determined that the final rule does not involve a collection of information pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

Small Business Regulatory Enforcement Fairness Act

The final rule relates to agency management or personnel, and the final rule is therefore not covered by the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA'') (5 U.S.C. 801 *et seq.*). 5 U.S.C. 804(3)(B).

List of Subjects in 5 CFR Part 3201

Conflict of interests, Ethical conduct, Extensions of credit and loans from FDIC-insured depository institutions, Government employees, Prohibitions on ownership of securities of FDIC-insured depository institutions.

■ For the reasons set forth in the preamble, the Board of Directors of the FDIC, with the concurrence of OGE, amends part 3201 of title 5 of the Code of Federal Regulations as follows:

PART 3201—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE FEDERAL DEPOSIT INSURANCE CORPORATION

■ 1. The authority citation for 5 CFR part 3201 is revised to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 12 U.S.C. 1819(a), 1822; 18 U.S.C. 212, 213; 26 U.S.C. 1043; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403, 2635.502, 2635.803.

■ 2. Paragraph (d) of § 3201.101 is revised to read as follows:

§ 3201.101 General.

* * * * *

(d) *Definitions.* For purposes of this part, the following definitions apply:

(1) *Affiliate*, as defined in 12 U.S.C. 1841(k), means any company that controls, is controlled by, or is under common control with another company.

(2) *Appropriate director* means the head of a Washington office or division or the highest ranking official assigned to a regional office in each division or the Ethics Counselor.

(3) *Covered employee* means:

(i) Members of the FDIC Board of Directors and any employee required to file a public or confidential financial disclosure under 5 CFR part 2634 who holds a position immediately subordinate to such Board member;

(ii) The director of any Washington division or office and the director of any regional office, and any employee required to file a public or confidential financial disclosure report under 5 CFR part 2634 who holds a position immediately subordinate to such director;

(iii) An FDIC examiner;

(iv) Any other FDIC employee whose duties and responsibilities include the examination of or the participation in the examination of any financial institution;

(v) Any other FDIC employee whose duties and responsibilities, as determined by the Chairman or Ethics Counselor after notice to the employee, require application of the prohibition on borrowing contained in § 3201.102 to ensure public confidence that the FDIC's programs are conducted impartially and objectively.

(4) *Employee* means an officer or employee, other than a special Government employee, of the Corporation, including a member of the Board of Directors appointed under the authority of 12 U.S.C. 1812(a)(1)(C). For purposes of 5 CFR part 2635 and §§ 3201.103 and 3201.104, employee includes any individual who, pursuant to a contract or any other arrangement, performs functions or activities of the Corporation, under the direct supervision of an officer or employee of the Corporation.

(5) *Ethics Counselor* means an officer or employee who is designated by the head of the agency to coordinate and manage the agency's ethics program, and includes the Corporation's Alternate Ethics Counselor.

(6) *Security* includes an interest in debt or equity instruments. The term includes, without limitation, a secured or unsecured bond, debenture, note, securitized assets, commercial paper, and all types of preferred and common stock. The term includes an interest or right in a security, whether current or contingent, a beneficial or legal interest derived from a trust, the right to acquire or dispose of any long or short position, an interest convertible into a security, and an option, right, warrant, put, or call with respect to a security. The term security does not include a deposit account.

(7) *State nonmember bank* means any State bank as defined in 12 U.S.C. 1813(e) that is not a member of the Federal Reserve System.

(8) *Subsidiary*, as defined in 12 U.S.C. 1813(w), means any company that is owned or controlled directly or indirectly by another company.

■ 3. Section 3201.102 is revised to read as follows:

§ 3201.102 Extensions of credit and loans from FDIC-insured institutions.

(a) *Credit subject to this section.* The prohibition, disqualification, and retention provisions of this section apply to a current or contingent financial obligation of the employee. For purposes of this section, a current or contingent financial obligation of an employee's spouse or minor child is considered to be an obligation of the employee.

(b) *Disqualification applicable to FDIC employees generally.* Except as provided in this section:

(1) No FDIC employee may participate in an examination, audit, visitation, review, or investigation, or any other particular matter involving an FDIC-insured institution, subsidiary or other person with whom the employee has an outstanding extension of credit.

(2) For employees, other than covered employees as defined in § 3201.101(d)(3), disqualification is not required if the credit was extended through the use of a credit card on the same terms and conditions as are offered to the general public.

(3) The Comptroller of the Currency and the Director of the Office of Thrift Supervision shall be disqualified from any matter pending before the FDIC Board of Directors to the same extent as an FDIC employee subject to paragraph (c) of this section.

(c) *Prohibited borrowing by covered employees.* (1) *Prohibition on covered employee borrowing*—Except as provided below, no covered employee shall, directly or indirectly, accept or become obligated on a loan or extension of credit, whether current or contingent, from any FDIC-insured State nonmember bank or its subsidiary or from an officer, director, or employee, of any FDIC-insured State nonmember bank or its subsidiary.

(2) *Exceptions:* (i) *Credit Cards.* A covered employee (or spouse or minor child of a covered employee) may obtain and hold a credit card account established under an open end consumer credit plan and issued by an FDIC-insured State nonmember bank or its subsidiary subject to the following conditions:

(A) The cardholder must satisfy all financial requirements for the credit card account that are generally applicable to all applicants for the same type of credit card account; and

(B) The terms and conditions applicable with respect to the account and any credit extended to the cardholder under the account are no more favorable generally to the cardholder than the terms and conditions that are generally applicable to credit card accounts offered by the same bank (or the same subsidiary) to other cardholders in comparable circumstances under open end consumer credit plans.

(ii) *Loans secured primarily by principal residence.* A covered employee (or a spouse or minor child of a covered employee) may obtain and hold a loan from an FDIC-insured State nonmember bank or its subsidiary subject to the following conditions:

(A) The loan is secured by residential real property that is the principal residence of the borrower. The borrower may retain the loan if the residential real property ceases to be the principal residence. However, any subsequent renewal or renegotiation of the original terms of such a loan must meet the requirements of this paragraph;

(B) The borrower may not apply for the loan while the covered employee participates in any examination, the review of any application, or any other supervisory or regulatory or other particular matter directly affecting the State nonmember bank or its subsidiaries;

(C) The borrower must satisfy all financial requirements for the loan that are generally applicable to all applicants for the same type of residential real property loan; and

(D) The terms and conditions applicable with respect to the loan and any credit extended to the borrower under the loan are no more favorable generally to the borrower than the terms and conditions that are generally applicable to residential real property loans offered by the same State nonmember bank or the same subsidiary to other borrowers in comparable circumstances for residential real property loans.

(3) *Disqualification of covered employees.* A covered employee shall not participate in an examination, audit, visitation, review, or investigation, or other particular matter involving an FDIC-insured depository institution or other person with whom the covered employee has an outstanding extension of credit, or with whom the covered employee is negotiating an extension of credit.

(i) *Payment dispute, delinquency, or other significant matter concerning credit card debt.* Disqualification is not required if the credit is extended through the use of a credit card. However, disqualification will be required when a covered employee is delinquent on payments, has a billing dispute, is negotiating with the institution, or has any other significant issue regarding the credit card debt. The covered employee must notify his or her supervisor and deputy ethics counselor of a dispute in writing.

(ii) *Primary residence mortgage loan.* Disqualification will be required if the covered employee is negotiating for, has an application pending for, or enters into a primary residence mortgage loan. This disqualification will cease when the loan is sold, even if the loan originator retains the loan servicing.

(4) *Other limitations on covered employees.* (i) A covered employee shall not accept or become obligated on an otherwise permissible loan if the disqualification arising from the credit relationship would materially impair the covered employee's ability to participate in matters that are central to the performance of the covered employee's official duties, or if the covered employee has been advised of an assignment to handle a matter involving that institution. (ii) Covered employees to whom the prohibitions in this section apply may not apply for a credit card or primary residence mortgage loan from a State nonmember bank or subsidiary that the covered employee is assigned to examine or participate in a matter involving that institution, or if such an assignment is imminent.

(5) *Pre-existing credit.* (i) This section does not prohibit a covered employee, or any FDIC employee who becomes a covered employee as a result of any reassignment of duties or position, from retaining a loan or extension of credit from a State nonmember bank or its subsidiary on its original terms if the loan or extension of credit was incurred prior to employment by the FDIC or as a result of the sale or transfer of a loan or credit to a State nonmember bank or its subsidiary or the conversion or merger of the lender into a State nonmember bank or its subsidiary. Any renewal or renegotiation of a pre-existing loan or extension of credit will be treated as a new loan or extension of credit subject to the prohibitions at paragraphs (c)(3) and (c)(4) of this section.

(ii) A covered employee may request that an exception be made to the prohibitions to permit renegotiation of a pre-existing loan or extension of credit. If a covered employee would experience financial or other hardship unless allowed to renegotiate a pre-existing loan or extension of credit, the covered employee may submit a written request to his or her supervisor and to the Ethics Counselor, describing the reasons for renegotiation, the original and the proposed terms and conditions, including whether the financial institution makes such terms generally available to the public, and any attempts by the covered employee to move the loan to a non-prohibited source. After consideration of the request, the covered employee's supervisor and the Ethics Counselor jointly may grant the waiver upon a finding that renegotiation is not prohibited by law, and that the waiver does not result in a loss of impartiality or objectivity or in misuse of the employee's position. To be effective, the waiver must be in writing.

(d) *Two-year prohibition on acceptance of credit from an FDIC-insured depository institution.* An FDIC employee shall not, directly or indirectly, accept or become obligated on any extension of credit from an FDIC-insured depository institution or its subsidiary for a period of two years from the date of the employee's last personal and substantial participation in an audit, resolution, liquidation, assistance transactions, supervisory proceeding, or internal agency deliberation affecting that particular institution, its predecessor or successor, or any subsidiary of such institution. This prohibition does not apply to credit obtained through the use of a credit card or a residential real property loan secured by the principal residence of the employee, subject to the same conditions, limitations, disqualification, and waiver procedures applicable to covered employees under paragraphs (c) and (e) of this section.

(e) *Waiver.* The Ethics Counselor may grant a written waiver from any provision of this section based on a determination made with the advice and legal clearance of the Legal Division that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law, and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality, or otherwise to ensure

confidence in the impartiality and objectivity with which the FDIC's programs are administered. A waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

■ 4. Section 3201.103 is revised to read as follows:

§ 3201.103 Prohibition on acquisition, ownership, or control of securities of FDIC-insured depository institutions and certain holding companies.

(a) *Prohibition on acquisition, ownership, or control.* Except as provided in paragraph (b) of this section, no employee, spouse of an employee, or minor child of an employee may acquire, own, or control, directly or indirectly, a security of any of the following:

(1) A bank or savings association that is insured by the Federal Deposit Insurance Corporation (FDIC);

(2) A bank holding company that is subject to supervision by the Federal Reserve Board (FRB);

(3) A savings and loan holding company that is subject to supervision by the Office of Thrift Supervision (OTS);

(4) A financial holding company that is subject to FRB supervision; or

(5) A company that:

(i) Owns or controls an FDIC-insured bank or savings association;

(ii) Is neither an FRB-supervised bank holding company, an OTS-supervised savings and loan holding company, nor an FRB-supervised financial holding company; and

(iii) Is either primarily engaged in banking or not publicly traded on a U.S. securities exchange.

(b) *Exceptions.* Notwithstanding the prohibitions of paragraph (a) of this section, but subject to the limitations of paragraph (c) of this section, an employee, or the spouse or minor child of an employee, may do any or all of the following:

(1) Acquire, own, or control the securities of a unitary thrift holding company (i.e., a savings and loan holding company that is subject to OTS supervision but whose principal business is neither banking nor activities closely related to banking);

(2) Own or control a security of an entity described in paragraph (a) of this section if the security was permitted to be retained by the employee under 12 CFR part 336 prior to May 25, 1995, was obtained prior to commencement of employment with the Corporation, or was acquired by a spouse prior to marriage to the employee;

(3) Own, or control a security of an entity described in paragraph (a) of this section if:

(i) The security was acquired by inheritance, gift, stock-split, involuntary stock dividend, merger, acquisition, or other change in corporate ownership, exercise of preemptive right, or otherwise without specific intent to acquire the security, or, by an employee's spouse or minor child as part of a compensation package in connection with his or her employment;

(ii) The employee makes full, written disclosure on FDIC form 2410/07 to the Ethics Counselor within 30 days of the commencement of employment or the acquisition of the interest; and

(iii) The employee is disqualified in accordance with 5 CFR part 2635, subpart D, from participating in any particular matter that affects his or her financial interests, or that of his or her spouse or minor child;

(4) Acquire, own, or control an interest in a publicly traded or publicly available investment fund provided that, upon initial or subsequent investment by the employee (excluding ordinary dividend reinvestment), the fund does not have invested, or indicate in its prospectus the intent to invest, more than 30 percent of its assets in the securities of one or more entities described in paragraph (a) of this section and the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund; and

(5) Use an FDIC-insured depository institution or an affiliate of an FDIC-insured depository institution as custodian or trustee of accounts containing tax-deferred retirement funds.

(c) *Divestiture.* Based upon a determination of substantial conflict under 5 CFR 2635.403(b), the Ethics Counselor may require an employee, or the spouse or minor child of an employee, to divest a security he or she is otherwise authorized to acquire, own, control, or use under paragraph (b) of this section.

(d) *Waiver.* The Ethics Counselor may grant a written waiver from any provision of this section based on a determination made with the advice and legal clearance of the Legal Division that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law, and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality, or otherwise to ensure confidence in the impartiality and objectivity with which the FDIC's programs are administered. A waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

By order of the Board of Directors.

Dated at Washington, DC, this 20th day of March, 2007.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Approved: April 10, 2007.

Robert I. Cusick,

Director, Office of Government Ethics.

[FR Doc. E7–7377 Filed 4–17–07; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–27898; Directorate Identifier 2007–NM–078–AD; Amendment 39–15029; AD 2007–07–05 R1]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is revising an existing airworthiness directive (AD), which applies to all Boeing Model 777 airplanes. That AD currently requires a one-time inspection to determine the part number of the left and right air supply and cabin pressure controllers (ASCPCs), and installation of new ASCPC software if necessary. This AD requires those same actions. This AD also revises the existing AD to allow installation of an ASCPC with additional versions of software installed and to correct a part number reference. This AD results from a report of an ASCPC failure during flight. We are issuing this AD to prevent an ASCPC failure that could stop airflow into the airplane, inhibit the cabin altitude warning message, and cause an incorrect display of cabin altitude. These failures could result in depressurization of the airplane without warning.

DATES: The effective date of this AD is April 18, 2007.

On April 18, 2007 (72 FR 15820, April 3, 2007), the Director of the Federal Register approved the incorporation by reference of Boeing Service Bulletin 777–36A0026, Revision 1, dated February 8, 2007.

We must receive any comments on this AD by June 18, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this AD:

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: David Webber, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6451; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

On March 21, 2007, we issued AD 2007–07–05, amendment 39–15010 (72 FR 15820, April 3, 2007). That AD applies to all Boeing Model 777 airplanes. That AD requires a one-time inspection to determine the part number of the left and right air supply and cabin pressure controllers (ASCPCs), and installation of new ASCPC software if necessary. That AD resulted from a report of an ASCPC failure during flight. The actions specified in that AD are intended to prevent an ASCPC failure that could stop airflow into the airplane, inhibit the cabin altitude warning message, and cause an incorrect display of cabin altitude. These failures could result in depressurization of the airplane without warning.

Actions Since AD Was Issued

Since we issued that AD, we have determined that additional versions of the ASCPC software should be permitted. In paragraph (i) of that AD (''Installation of Certain OPS Software Prohibited''), we cited a specific part number of operational program software (OPS) that must be installed in ASCPCs before they can be installed on any airplane as of the effective date of that AD. By citing that specific part number, we inadvertently prohibited use of later, acceptable versions of the OPS. This was not our intent.

We have also determined that, in that same paragraph, there is a typographical error resulting in an incorrect ASCPC part number.

FAA's Determination and Requirements of This AD

The unsafe condition described previously is likely to exist or develop on other airplanes of the same type design. For this reason, we are issuing this AD to revise AD 2007–07–05. This new AD retains the requirements of the existing AD. This AD also revises the existing AD to allow installation of an ASCPC with additional versions of software installed and to correct a part number reference.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed in the **ADDRESSES** section. Include ''Docket No. FAA–2007–27898; Directorate Identifier 2007–NM–078–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD that might suggest a need to modify it.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

Examining the Dockets

You may examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–15010 (72 FR 15820, April 3, 2007) and adding the following new airworthiness directive (AD):

2007–07–05 R1 Boeing: Amendment 39–15029. Docket No. FAA–2007–27898; Directorate Identifier 2007–NM–078–AD.

Effective Date

(a) The effective date of this AD is April 18, 2007.

Affected ADs

(b) This AD revises AD 2007–07–05.

Applicability

(c) This AD applies to all Boeing Model 777–200, –200LR, –300, and –300ER series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from a report of an air supply and cabin pressure controller (ASCPC) failure during flight. We are issuing this AD to prevent an ASCPC failure that could stop airflow into the airplane, inhibit the cabin altitude warning message, and cause an incorrect display of cabin altitude. These failures could result in depressurization of the airplane without warning.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection to Determine Part Number (P/N) of the ASCPCs

(f) For all airplanes: Within 90 days after the effective date of this AD, perform an inspection of the left and right ASCPCs to determine the part number.

ASCPC Software Installation

(g) For airplanes on which any ASCPC having P/N 1152972–4 is found during the inspection required by paragraph (f) of this AD: Within 90 days after the effective date of this AD, install new ASCPC operational program software (OPS) in accordance with the Accomplishment Instructions of Boeing Service Bulletin 777–36A0026, Revision 1, dated February 8, 2007.

Installation of Certain OPS Prohibited

(h) As of the effective date of this AD, installation of OPS P/N 3673–GRS–101–00, P/N 3670–GRS–102–00, or P/N 3671–GRS–103–00 is prohibited.

(i) As of the effective date of this AD, no person may install an ASCPC, P/N 1152972–4, on any airplane, unless it has had ASCPC OPS version P/N 3676–GRS–104–00 or later installed in accordance with paragraph (g) of this AD.

Credit for Actions Done Using Previous Service Information

(j) Actions accomplished before the effective date of this AD in accordance with Boeing Alert Service Bulletin 777–36A0026, dated December 19, 2006, are considered acceptable for compliance with the corresponding actions specified in this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Material Incorporated by Reference

(l) You must use Boeing Service Bulletin 777–36A0026, Revision 1, dated February 8, 2007, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document on April 18, 2007 (72 FR 15820, April 3, 2007). Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for a copy of this service information. You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 12, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 07–1936 Filed 4–16–07; 11:59 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91 and 136

[Docket No. FAA–1998–4521]

National Air Tour Safety Standards

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of office of management and budget approval for information collection.

SUMMARY: This notice announces the Office of Management and Budget's (OMB) approval of the information collection requirement in the final rule published on February 13, 2007 (72 FR 6884). The sections of the final rule pending approval of this information collection request are effective upon publication of this notice.

DATES: FAA received OMB approval for the information collection requirement in the Final Rule on April 10, 2007. The compliance date for information collection requirements in 14 CFR 91.146, 91.147, 136.7, and 136.13 is April 18, 2007.

FOR FURTHER INFORMATION CONTACT: Alberta Brown, Air Transportation Division, AFS–200, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8166; facsimile: (202) 267–8229; e-mail: *alberta.brown@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On February 13, 2007, the FAA published the final rule, ''National Air Tour Safety Standards,'' in the **Federal Register**. The rule standardized requirements for air tour operations and consolidated air tour safety standards in Title 14 of the Code of Federal Regulations part 136. In the **DATES** section of the final rule, we noted that affected parties did not need to comply with the information collection requirements in certain sections of the rule until the Office of Management and Budget (OMB) approved the FAA's request to collect the information.

In accordance with the Paperwork Reduction Act, OMB approved the FAA's request for new information collection on April 10, 2007, and assigned the information collection OMB Control Number 2120–0717. The control number was not available to include when the final rule was published, thus necessitating this notice. The FAA request was approved by OMB without change and expires on April 30, 2010.

49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 46105, grants authority to the Administrator to publish this notice. The final rule (72 FR 6884) became effective on March 15, 2007, and the compliance date for information collection requirements in 14 CFR 91.146, 91.147, 136.7, and 136.13 is April 18, 2007.

Issued in Washington, DC, on April 12, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E7–7300 Filed 4–17–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AM12

Veterans' Education: Transfer of Montgomery GI Bill-Active Duty Entitlement to Dependents; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Correcting amendment.

SUMMARY: The Department of Veterans Affairs (VA) published a document in the **Federal Register** on December 18, 2006 (71 FR 75672), implementing VA's authority under the National Defense Authorization Act for Fiscal Year 2002 and the Bob Stump National Defense Authorization Act for Fiscal Year 2003 to provide educational assistance to dependents eligible for transferred Montgomery GI Bill—Active Duty (MGIB) entitlement. In that document, we assigned the wrong paragraph designations to three paragraphs in § 21.7136(d)(6). This document corrects that error.

DATES: *Effective Date:* April 18, 2007. *Applicability Date:* December 18, 2006.

FOR FURTHER INFORMATION CONTACT: Devon E. Seibert, Management and Program Analyst, Education Service, Veterans Benefits Administration, Department of Veterans Affairs (225C), 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–9677. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: The VA published a document in the **Federal Register** on December 18, 2006, 72 FR 75672, revising its education regulations to implement VA's authority under the National Defense Authorization Act for Fiscal Year 2002 and the Bob Stump National Defense Authorization Act for Fiscal Year 2003 to provide educational assistance to dependents eligible for transferred Montgomery GI Bill-Active Duty entitlement. In that document, we assigned the wrong paragraph designations for three paragraphs in § 21.7136(d)(6). This document corrects that error by redesignating paragraphs (d)(6)(v) through (d)(6)(vii) as paragraphs (d)(6)(i) through (d)(6)((iii), respectively.

List of Subjects in 38 CFR Part 21

Administrative practice and procedure, Armed forces, Civil rights, Claims, Colleges and universities, Conflicts of interest, Education, Employment, Grant programs-education, Grant programs-veterans, Health care, Loan programs-education, Loan programs-veterans, Manpower training programs, Reporting and recordkeeping requirements, Schools, Travel and transportation expenses, Veterans, Vocational education, Vocational rehabilitation.

Approved: April 12, 2007.

William F. Russo,

Director of Regulations Management.

■ For the reasons set out in the preamble, VA is correcting 38 CFR part 21 (subpart K) as set forth below:

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

Subpart K—All Volunteer Force Educational Assistance Program (Montgomery GI Bill—Active Duty)

■ 1. The authority citation for part 21, subpart K continues to read as follows:

Authority: 38 U.S.C. 501(a), chs. 30, 36, unless otherwise noted.

■ 2. Amend § 21.7136 by redesignating paragraphs (d)(6)(v) through (d)(6)(vii) as (d)(6)(i) through (d)(6)(iii), respectively.

[FR Doc. E7–7338 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2005–UT–0001; UT–001–0052a; EPA–R08–OAR–2006–0564; EPA–R08–OAR–2005–UT–0006; FRL–8300–1]

Approval and Promulgation of Air Quality Implementation Plans; State of Utah; State Implementation Plan Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical corrections.

SUMMARY: When EPA approved Utah's Rule Recodification on February 14, 2006, we inadvertently incorporated by reference rules into the State Implementation Plan (SIP). When EPA approved Utah's Continuous Emission Monitoring Program on May 15, 2003, we inadvertently failed to remove the older version of the Continuous Emission Monitoring Program rule from the SIP. When EPA approved Revisions to the Utah Administrative Code on November 1, 2006, we inadvertently incorporated by reference incorrect state rules. Finally, when EPA approved Carbon Monoxide provisions for Provo, we inadvertently failed to remove the older version of Control Measures For Area and Point Sources—Carbon Monoxide—Provo. EPA is correcting these errors with this document.

DATES: This rule is effective on May 18, 2007.

FOR FURTHER INFORMATION CONTACT: Kerri Fiedler, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, phone (303) 312–6493, and e-mail at: *fiedler.kerri@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Correction
  a. Rule Recodification
  b. Continuous Emission Monitoring Program
  c. Revisions to the Utah Administrative Code
  d. Carbon Monoxide Provisions for Provo
II. Statutory and Executive Order Reviews

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The word *State* means the State of Utah, unless the context indicates otherwise.

Section 553 of the Administrative Procedures Act, 5 U.S.C. 553(b)(B) and (d)(3), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comments.

Section 553(d)(3) provides that prior notice is not required with good cause. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because we are merely correcting incorrect text in previous rulemakings. Thus, notice and public comment procedures are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B) and (d)(3).

I. Correction

a. Rule Recodification

On November 2, 2005 (70 FR 66264), EPA approved the removal of Rule R307–301 from the Federally-approved SIP as part of Utah's Redesignation of Provo to Attainment of the Carbon Monoxide standard. When EPA approved Utah's Rule Recodification on February 14, 2006 (71 FR 7679), Rules R307–301–1, R307–301–2, and R307–301–4 through R307–301–14 were inadvertently incorporated by reference back into Utah's federally-approved SIP. This corrections rule simply removes the following from 40 CFR 52.2320(c)(59)(i)(A): ''R307–301–1, R307–301–2, and R307–301–4 through R307–301–14 effective November 12, 1998.''

Furthermore, on February 14, 2006 (71 FR 7679), EPA inadvertently incorporated by reference Rule R307–302–2(4). In the proposed rule on October 13, 2005 (70 FR 59681), page 59684 clearly states EPA is approving Rule R307–302 with the exception of rule section R307–302–2(4). Currently 40 CFR 52.2320(c)(59)(i)(A) contains the following phrase: ''R307–302–1, R307–302–2 and R307–302–4 effective September 15, 1998.'' This corrections rule simply revises the phrase to read as follows: ''R307–302–1, R302–302–2 (except paragraph (4)) and R307–302–4 effective September 15, 1998.''

b. Continuous Emission Monitoring Program

On December 14, 1994 (59 FR 64326), EPA approved Rule R307–1–4.06, ''Continuous Emission Monitoring Systems Program (CEMSP).'' When EPA approved a revision to Utah's Continuous Emission Monitoring Program (CEM), Rule R307–170 on May 15, 2003 (68 FR 26210), Rule R307–1–4.06 was superseded and replaced but was not removed from Utah's federally-approved SIP. This action simply removes Rule R307–1–4.06 from Utah's federally-approved SIP.

c. Revisions to the Utah Administrative Code

On November 1, 2006 (71 FR 64125), EPA approved changes to Rules R307–170–7(1); R307–170–4; R307–170–5(7); R307–170–7(6), R307–170–7(6)(a) and (b); and R307–170–9 sections (5)(a) and (b), (6)(b), (7)(b), and (9)(a). There is a typographical error and Rule R307–170–9(5)(b) should have been Rule R307–170–9(5)(d), which removes a duplicate ''and'' from Utah's rule. In addition, revisions to Rules R307–170–5(1)(b) and R307–170–9(7)(a)(i) should have been included in the November 1, 2006 approval. Rule R307–170–5(1)(b) deletes an ''a'' and adds an ''A''. Rule R307–170–9(7)(a)(i) deletes a space and adds a dash (''-''). Currently 40 CFR 52.2320(c)(64)(i)(A) reads: ''Utah Administrative Code sections: R307–170–7(1); 307–170–4; R307–170–5(7); R307–170–7(6); R307–170–7(6)(a) and (b); and in R307–170–9 sections (5)(a) and (b), (6)(b), (7)(b), and (9)(a); effective January 5, 2006.'' This action simply corrects 40 CFR 52.2320(c)(64)(i)(A) to read as follows: ''Utah Administrative Code sections: R307–170–7(1); 307–170–4; R307–170–5(*1*)(*b*); R307–170–5(7); R307–170–7(6); R307–170–7(6)(a) and (b); and in R307–170–9 sections (5)(a) and (d), (6)(b), (7)(*a*)(*i*), (7)(b), and (9)(a); effective January 5, 2006.''

d. Carbon Monoxide Provisions for Provo

On June 25, 2003 (68 FR 37744), EPA approved Utah SIP Control Measures for Area and Point Sources—Carbon Monoxide—Provo—Section IX.C.6. When EPA approved Section IX.C.6—Carbon Monoxide Provisions for Provo on November 2, 2005 (70 FR 66264) EPA inadvertently failed to remove the older SIP Section IX.C.6 from Utah's federally-approved SIP. This action simply removes the June 25, 2003 approved version of Utah SIP Control Measures for Area and Point Sources—Carbon Monoxide—Provo—Section IX.C.6 from Utah's federally-approved SIP because it has been replaced by a newer version.

II. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4, 209 Stat. 48 (1995)). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA.

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal Standard.

This technical correction action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issues under the Executive Order. This ruled does not impose an

information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public comment procedures are impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement, 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of May 18, 2007. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. These corrections to the identification of plan for Utah are not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: April 9, 2007.

Kerrigan G. Clough,

Acting Regional Administrator, Region VIII.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart TT—UTAH

■ 2. Section 52.2320 is amended as follows:

■ a. In paragraph (c)(59)(i)(A) by removing the phrase ''R307–301–1, R307–301–2, and R307–301–4 through R307–301–14 effective November 12, 1998;'' and by revising the phrase that reads ''R307–302–1, R307–302–2 and R307–302–4 effective September 15, 1998'' to read ''R307–302–1, R302–302–2 (except paragraph (4)) and R307–302–4 effective September 15, 1998.''

■ b. By revising paragraph (c)(64)(i)(A) as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

(64) * * *

(i) * * *

(A) Utah Administrative Code sections: R307–170–7(1); 307–170–4; *R307–170–5(1)(b);* R307–170–5(7); R307–170–7(6); R307–170–7(6)(a) and (b); and in R307–170–9 sections (5)(a) and (d), (6)(b), (*7*)(*a*)(*i*), (7)(b), and (9)(a); effective January 5, 2006.

■ 3. Section 52.2352 is amended by adding paragraph (f) to read as follows:

§ 52.2352 Change to approved plan.

* * * * *

(f) Utah Administrative Code (UAC) rule R307–1–4.06, Continuous Emission Monitoring Systems Program (CEMSP), is removed from Utah's approved State Implementation Plan (SIP). This rule has been superseded and replaced by rule R307–170, Continuous Emission Monitoring Program.

[FR Doc. E7–7201 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63 and 65

[EPA–HQ–OAR–2004–0094; FRL–8301–2]

RIN 2060–AO40

National Emission Standards for Hazardous Air Pollutants: General Provisions: Notice of Decision Denying Petition for Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of decision denying petition for reconsideration.

SUMMARY: On April 20, 2006, EPA published final rules entitled, ''National Emission Standards for Hazardous Air Pollutants: General Provisions.'' Following that final action, the Administrator received a petition for reconsideration from Coalition for a Safe Environment (CFASE). CFASE's petition for reconsideration can be found in the rulemaking docket under Docket ID No. EPA–HQ–OAR–2004–0094. After carefully considering the petition and information in the rulemaking docket, EPA is denying CFASE's petition for reconsideration.

ADDRESSES: The docket for EPA's denial of CFASE's petition for reconsideration is Docket ID No. EPA–HQ–OAR–2004–0094. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, i.e., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center, Docket ID No. EPA–HQ–OAR–2004–0094, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Rick Colyer, U.S. EPA Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Program Design Group (D205–02), Research Triangle Park, NC 27711; telephone number (919) 541–5262; fax number (919) 541–5600; e-mail address: *colyer.rick@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

In addition to being available in the docket, an electronic copy of today's notice of EPA's decision denying CFASE's petition for reconsideration will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of this notice will be posted on the TTN's policy and guidance page for newly promulgated rules at *http://www.epa.gov/ttn/oarpg*. The TTN provides information and technology exchange in various areas of air pollution control.

Outline. The information presented in this preamble is organized as follows:

I. General Information
II. Background Information
III. Basis for Denial of Reconsideration

II. Background Information

On April 20, 2006, EPA issued certain amendments to the 40 CFR parts 63 and 65 startup, shutdown, and malfunction (SSM) general provisions requirements affecting sources subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP). On June 19, 2006, EarthJustice filed a petition for review challenging those amendments in the

United States Court of Appeals for the District for Columbia Circuit on behalf of Environmental Integrity Project, Friends of Hudson, Louisiana Environmental Action Network and Coalition for a Safe Environment (CFASE). On the same day, CFASE filed a petition for administrative reconsideration with EPA pursuant to section 307(d)(7)(B).

CFASE appears to base its petition for reconsideration on a claim that it did not receive adequate notice of certain changes EPA made in the final rule to the SSM recordkeeping and reporting requirements. EPA made changes to the recordkeeping and reporting requirements in the final rule to address comments on the proposed rule submitted by EarthJustice and Environmental Integrity Project. In comments on the proposed rule, EarthJustice and Environmental Integrity Project asserted that the proposed rule's elimination of the requirement that a source implement an SSM plan renders the SSM rule's general duty to minimize emissions vague and unenforceable and violates the Clean Air Act (CAA) Title V requirement that permits contain enforceable limits and standards and conditions necessary to assure compliance. (Docket number EPA–HQ–OAR–2004–0094, items 29 through 32.)

The General Provisions to 40 CFR part 63 require that ''at all times, including periods of startup, shutdown, and malfunction, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. During a period of startup, shutdown, or malfunction, this general duty to minimize emissions requires that the owner or operator reduce emissions from the affected source to the greatest extent which is consistent with safety and good air pollution control practices.'' [1] In the proposed rule preamble, we explained that the reporting and recordkeeping requirements would allow the permitting authority and the public to determine compliance with the general duty clause. 70 FR at 43394 (July 29, 2005). However, in an effort to address the above-mentioned concerns raised by commenters, we reevaluated the recordkeeping and reporting requirements and made minor revisions to those requirements to clarify that the information required in SSM records and reports include a description of the ''actions taken'' at the facility during SSM events that involve an exceedance of the applicable standard.[2] The final rule preamble explained the revisions as follows:

> With these clarifications, any time there is an exceedance of an emission limit (or could have been in the case of malfunctions) and thus a possibility that the general duty requirement was violated, there will be a report filed that will describe what actions were taken to minimize emissions that will be available to the public.
>
> Any member of the public could use the information in these reports to evaluate whether adequate steps were taken to meet the general duty requirement. This information is likely to be of as much if not more use in determining compliance with the general duty requirement than a facility's general SSM plan because the information will be specific to the particular SSM event that caused the exceedance.

71 FR 20448 (April 20, 2006).

In its petition, CFASE argues that EPA's reliance on the revised recordkeeping and reporting requirements to assure compliance with the general duty to minimize emissions is insufficient. CFASE further argues that the SSM rule violates the CAA section 504(a) requirement that title V permits contain ''conditions as are necessary to assure compliance'' with the general duty to minimize emissions and that reliance on reporting alone does not ''assure compliance.'' CFASE also asserts that a vague generalized requirement such as the general duty to minimize emissions must be supplemented with permit conditions sufficient to explain how the requirement applies specifically to the permitted facility.

III. Basis for Denial of Reconsideration

EPA denies CFASE's petition for reconsideration. Section 307(d)(7)(B) of the CAA requires EPA to convene a proceeding for reconsideration based on objections that were not raised during the public comment period only if ''it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment * * * and if such objection is of central relevance to the outcome of the rule * * *''

Petitioner has failed to establish that the objections raised are based on grounds that ''arose after the public comment period.'' As noted above, the preamble to the proposed rule clearly articulates EPA's reliance on recordkeeping and reporting to allow the permitting agency and the public to determine compliance with the general duty to minimize emissions. Specifically, the proposal provides:

> These periodic and immediate SSM reports provide the permitting authority with adequate information to determine if the facility has SSM problems above and beyond what might normally be expected. The types and frequency of SSM events will vary from source category to source category. Sources that report much higher number of SSM events than other sources within the same source category would be subject to higher scrutiny by the permitting authority, by EPA, and presumably by the public. Inspectors would examine the facility's records and its SSM plan to determine its adequacy and whether it conformed to the general duty clause. If not, the facility could be cited for violating the general duty clause and required to revise its plan to minimize emissions to the satisfaction of the permitting authority. As such, the reports identify potential problems that can be followed up with appropriate action.

70 FR at 43394.

Nor were CFASE's objections to the recordkeeping and reporting requirements ''impracticable to raise'' during the public comment period. Indeed, the arguments raised by CFASE in its petition for reconsideration are merely a variation of the arguments raised in its comments on the proposal. The revisions to regulatory language made in the final rule were made by EPA in direct response to the comments of EarthJustice and Environmental Integrity project concerning enforceability of the general duty to minimize emissions.

As explained in the preamble to the proposed and final rules (70 FR at 43994 and 71 FR at 20448–9), the recordkeeping and reporting requirements adequately assure compliance with the general duty to minimize emissions. As we explained in the preamble to the proposed rule, the general duty clause is the applicable requirement under MACT standards for emission reductions during periods of SSM and ''* * * is designed to recognize that technology-based standards may not always be met, as technology fails occasionally beyond the control of the owner or operator * * *. If standards cannot be met during a

[1] This petition denial describes the general duty to minimize emissions as it applies during SSM events and does not address the application of the general duty to minimize emissions at other times.

[2] EPA responded to the comments by revising 40 CFR 63.10(d)(5)(i) and (ii) to require that a description of actions taken to minimize emissions be included in SSM reports whether or not the SSM plan was followed. EPA also revised the recordkeeping requirement at 40 CFR 63.10(b)(2)(v)(the requirement to keep a record of ''all information necessary to demonstrate conformance'' with the SSM plan when actions taken during SSM events are consistent with the SSM plan) to require that such records include all actions taken during the SSM event to minimize emissions. 70 FR at 20448.

period of SSM, then the owner or operator must take steps to minimize emissions to the extent practicable.'' 70 FR at 43993.

The exception to technology-based emission standards during SSM events, which applies when a source cannot meet the technology-based standard using all practicable steps to minimize emissions that are consistent with safety and good air pollution control practices, is appropriate and may be necessary to preserve the reasonableness of the underlying MACT standards. *Essex Chemical Corporation* v. *EPA*, 486 F.2d. 427, 432–33 (D.C. Cir 1973) (addressing exemption from New Source Performance Standards during SSM events); *Portland Cement Association* v. *Ruckelshaus*, 486 F.2d. 375, 398–99 (D.C. Cir. 1973) (same); *Marathon Oil* v. *EPA*, 564 F.2d. 1253, 1272–73 (9th Cir. 1977) (discussing need to provide upset defense for technology-based effluent limits to account for technology failure).

As discussed above and in the preamble to the proposed and final rules, the general duty to minimize emissions is sufficiently specific (71 FR 20448–49), and the SSM recordkeeping and reporting requirements are sufficient to assure compliance with the general duty clause. We note that in the Title V context, EPA's regulations specifically provide that recordkeeping requirements can adequately assure compliance. In particular, 40 CFR 70.6(a)(3)(i), which implements the statutory requirement of section 504(a) of the CAA, specifies that periodic testing and monitoring to determine compliance with an applicable requirement ''may consist of recordkeeping designed to serve as monitoring.'' Moreover, 40 CFR 70.6(a)(3)(i)(b) (which requires title V permits to include monitoring and testing provisions when an underlying applicable requirement does not contain provisions) specifies that ''[r]ecordkeeping provisions may be sufficient to meet the requirements of this paragraph (a)(3)(i)(B).''

Dated: April 12, 2007.

Stephen L. Johnson,

Administrator.

[FR Doc. E7–7362 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 07–1447; RM–10798]

Radio Broadcasting Services; Annville, Manchester, Mt. Vernon, West Liberty, KY

AGENCY: Federal Communications Commission.

ACTION: Final rule; denial of petition for reconsideration.

SUMMARY: This document denies a Petition for Reconsideration filed jointly by Vernon R. Baldwin, Inc., Morgan County Industries, Inc., and Vernon R. Baldwin (''Petitioners'') directed to a letter which returned their Joint Petition for Rule Making (''Joint Petition''). The Joint Petition was defective because the proposed site at Mt. Vernon failed to provide a 70 dBu signal over the entire community due to terrain obstruction. This document finds that it is not in the public interest to allow Petitioners on reconsideration to reinstate and amend their Joint Petition with a new site because a Petition for Rule Making must be technically correct at the time of filing. With this action, the proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order*, adopted March 28, 2007, and released March 30, 2007. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, and Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *www.BCPIWEB.com.* This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of this *Memorandum Opinion and Order* to the Government Accountability Office, pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the petition for reconsideration was denied.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division Media Bureau.

[FR Doc. E7–7257 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[WT Docket No. 99–87; RM 9332; FCC 07–39]

Implementation of Sections 309(j) and 337 of the Communications Act of 1934 as Amended; Promotion of Spectrum Efficient Technologies on Certain Part 90 Frequencies

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) declines, for now, to establish a schedule for Private Land Mobile Radio (PLMR) systems in the 150–174 MHz and 421–512 MHz bands to transition to 6.25 kHz technology; and revises the implementation date of the 6.25 kHz requirement for equipment certification from January 1, 2005 to January 1, 2011.

DATES: Effective May 18, 2007.

FOR FURTHER INFORMATION CONTACT: Melvin Spann, *Melvin.Spann@FCC.gov,* Mobility Division, Wireless Telecommunications Bureau at (202) 418–1333.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Third Report and Order* in WT Docket No. 99–87 (*Third Report and Order*), FCC 07–39, adopted on March 22, 2007, and released on March 26, 2007. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by sending an e-mail to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

1. The *Third Report and Order* addresses issues raised in the *Second*

Report and Order and Second Further Notice of Proposed Rule Making, (2nd R&O and 2nd FNPRM) and *Third Memorandum Opinion and Order, Third Further Notice of Proposed Rule Making and Order (3rd MO&O, 3rd FNPRM and Order)* in this proceeding. The Commission takes the following significant actions in the *Third Report and Order:* (i) declines to establish a schedule for PLMR systems in the 150–174 MHz and 421–512 MHz bands to transition to 6.25 kHz technology, and (ii) revises the implementation date of the 6.25 kHz requirement for equipment certification from January 1, 2005 to January 1, 2011.

I. Procedural Matters

A. Paperwork Reduction Act Analysis

2. The *Third Report and Order* does not contain any new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

B. Report to Congress

3. The Commission will send a copy of this *Third Report and Order* in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

C. Final Regulatory Flexibility Analysis

4. As required by the Regulatory Flexibility Act (RFA), *see* 5 U.S.C. 604, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) of the possible impact of the rule changes contained in this *Third Report and Order* on small entities. The Commission's Consumer Information Bureau, Reference Information Center, will send a copy of this *Third Report and Order,* including the FRFA Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Need for, and Objectives of, the Third Report and Order

5. The *Third Report and Order* addresses comments in response to the *Third Further Notice of Proposed Rule Making,* in WT Docket 99–87; FCC 04–292 at 70 FR 34666, concerning a contemplated mandatory transition to 6.25 kHz technology for Private Land Mobile Radio (PLMR) users. In the *Third Report and Order,* we change the implementation date of 47 CFR 90.203(j)(4)-(5) from January 1, 2005, to January 1, 2011. The rule change reduces burdens on equipment manufacturers and furthers the Commission's objectives to encourage the development and use of increasingly spectrally efficient technology. Once the rule change becomes effective, applications for equipment certification received on or after January 1, 2011, will be granted only if the equipment either (1) is capable of operating on 6.25 kHz channels, or (2) meets a narrowband efficiency standard, *i.e.*, one channel per 6.25 kHz (voice) or 4800 bits per second per 6.25 kHz (data).

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

6. No comments or reply comments were filed in direct response to the IRFA. The Commission has, however, reviewed the general comments that may impact small businesses. Much of the potential impact on small businesses arose from the previous requirement that applications for equipment certification received on or after January 1, 2005, will be granted only if the equipment either (1) is capable of operating on 6.25 kHz channels, or (2) meets a narrowband efficiency standard, *i.e.*, one channel per 6.25 kHz (voice) or 4800 bits per second per 6.25 kHz (data). The burdens and hardships associated with equipment manufacturers meeting this requirement were cited in opposition to this requirement.

Description and Estimate of the Number of Small Entities To Which Rules Will Apply

7. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data. A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 2002, there were approximately 1.6 million small organizations. The term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States. We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

8. The rule change effectuated by this *Third Report and Order* applies to manufacturers of radio equipment designed to operate on private land mobile frequencies in the 150–174 MHz and 421–512 MHz bands. The rule change and decisions herein also have a nominal, merely indirect application to users of Public Safety Radio Pool services and private radio licensees that are regulated under part 90 of the Commission's rules.

9. *Equipment Manufacturers.* We anticipate that at least six radio equipment manufacturers will be affected by our decisions in this proceeding. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees. According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 establishments had employed less than 500, and an additional 13 had employed 500 to 999. Thus, under this size standard, the majority of firms can be considered small.

10. *Public safety services and Governmental entities.* Public safety radio services include police, fire, local governments, forestry conservation, highway maintenance, and emergency medical services. The SBA rules contain a definition for small radiotelephone

(wireless) companies that encompass business entities engaged in radiotelephone communications employing no more that 1,500 persons. There are a total of approximately 127,540 licensees within these services. Governmental entities as well as private businesses comprise the licensees for these services. The RFA also includes small governmental entities as a part of the regulatory flexibility analysis. As noted, under the RFA, the term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States. We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

11. *Estimates for PLMR Licensees.* Private land mobile radio systems serve an essential role in a vast range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories. Because of the vast array of PLMR users, the Commission has not developed a definition of small entities specifically applicable to PLMR users, nor has the SBA developed any such definition. The SBA rules do, however, contain a definition for small radiotelephone (wireless) companies. Included in this definition are business entities engaged in radiotelephone communications employing no more that 1,500 persons. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of ''Paging'' and ''Cellular and Other Wireless Telecommunications.'' Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year. Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more. Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year. Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more. Thus, under this second category and size standard, the majority of firms can, again, be considered small. Thus, under this size standard, the majority of firms can be considered small. For the purpose of determining whether a licensee is a small business as defined by the SBA, each licensee would need to be evaluated within its own business area. The Commission's fiscal year 1994 annual report indicates that, at the end of fiscal year 1994, there were 1,101,711 licensees operating 12,882,623 transmitters in the PLMR bands below 512 MHz.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

12. Equipment manufacturers need to make note of the new implementation date of January 1, 2011, for 47 CFR 90.203(j)(4)-(5) of the Commission's Rules, as established in this *Third Report and Order*. Applications for equipment certification and received on or after January 1, 2011, will be granted only if the equipment either (1) is capable of operating on 6.25 kHz channels, or (2) meets a narrowband efficiency standard, *i.e.*, one channel per 6.25 kHz (voice) or 4800 bits per second per 6.25 kHz (data). We believe that both small and large entities will encounter the same proportional costs to comply with these requirements.

Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

13. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

14. The only rule change we adopt herein is to delay the implementation date of our certification requirements from January 1, 2005, to January 1, 2011. Applications for equipment certification received on or after January 1, 2011, will be granted only if the equipment either (1) is capable of operating on 6.25 kHz channels, or (2) meets a narrowband efficiency standard, *i.e.*, one channel per 6.25 kHz (voice) or 4800 bits per second per 6.25 kHz (data). This rule change reduces the impact on equipment manufacturers of the prior rule, which required compliance sooner. We delayed the implementation date because a majority of commenters believed that enforcing an equipment authorization cut-off now would place onerous burdens on manufacturers. We anticipate that small licensees will experience little impact as a result of this rule change. By 2011, licensees in the market for new equipment will have a choice between 12.5 kHz-capable and 6.25 kHz-capable equipment.

15. We investigated alternatives to the January 1, 2011, implementation date of our certification requirements, including elimination of the requirements, as requested by some commenters. We rejected earlier dates because they might not allow enough time for 6.25 kHz standards to be finalized. We believe that earlier dates would not provide significant relief to equipment manufacturers, and that they would incur excessive costs to meet our certification requirements. Next, we considered dates after 2011, as well as eliminating our 6.25 kHz equipment certification requirements completely. While we realize that these options would further minimize the economic impact on equipment manufacturers, we rejected these options they would excessively delay our objective to encourage the development and use of spectrally efficient technology.

D. Report to Congress

16. The Commission will send a copy of this *Third Report and Order* in WT Docket No. 99–87, including the Final Regulatory Flexibility Analysis, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the *Third Report and Order*, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the SBA. A copy of the *Third Report and Order* and the Final Regulatory Flexibility Analysis (or summaries thereof) will also be published in the **Federal Register**.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 90 as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 1. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

■ 2. Amend § 90.203 by revising paragraph (j)(4) introductory text and paragraph (j)(5); and removing paragraph (j)(6); and by redesignating paragraphs (j)(7) through (j)(11) as (j)(6) through (j)(10) to read as follows:

§ 90.203 Certification required.

* * * * *

(j) * * *

(4) Applications for part 90 certification of transmitters designed to operate on frequencies in the 150.8–162.0125 MHz, 173.2–173.4 MHz, and/or 421–512 MHz bands, received on or after January 1, 2011, except for hand-held transmitters with an output power of two watts or less, will only be granted for equipment with the following channel bandwidths:

* * * * *

(5) Applications for part 90 certification of transmitters designed to operate on frequencies in the 150.8–162.0125 MHz, 173.2–173.4 MHz, and/or 421–512 MHz bands, received on or after January 1, 2011, must include a certification that the equipment meets a spectrum efficiency standard of one voice channel per 6.25 kHz of channel bandwidth. Additionally, if the equipment is capable of transmitting data, has transmitter output power greater than 500 mW, and has a channel bandwidth of more than 6.25 kHz, the equipment must be capable of supporting a minimum data rate of 4800 bits per second per 6.25 kHz of channel bandwidth.

* * * * *

[FR Doc. E7–7252 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 070404078–7078–01; I.D. 082806B]

RIN 0648–AV52

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Biennial Specifications and Management Measures; Inseason Adjustments

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

ACTION: Final rule; inseason adjustments to groundfish management measures; request for comments.

SUMMARY: This final rule takes two actions: It establishes the 2007 harvest specifications for Pacific whiting (whiting) in the U.S. exclusive economic zone (EEZ) and state waters off the coasts of Washington, Oregon, and California; and, it announces inseason changes to management measures in the commercial and recreational Pacific Coast groundfish fisheries. These actions are authorized by the Pacific Coast Groundfish Fishery Management Plan (FMP). The 2007 whiting harvest specifications include the level of the acceptable biological catch (ABC), optimum yield (OY), tribal allocation, and allocations for the non-tribal commercial whiting sectors, and are intended to establish allowable harvest levels of whiting based on the best available scientific information. The inseason changes to fishery management measures are intended to allow fisheries to access more abundant groundfish stocks while protecting overfished and depleted species, and to reduce possible confusion to the public over differing state and Federal regulations.

DATES: Effective April 17, 2007. Comments on this rule must be received no later than 5 p.m., local time on May 18, 2007.

ADDRESSES: You may submit comments, identified by I.D. 082806B by any of the following methods:

- E-mail: *WhitingABCOYInseason1.nwr@noaa.gov.* Include I.D. 082806B in the subject line of the message.
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 206–526–6736, Attn: Gretchen Arentzen
- Mail: D. Robert Lohn, Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070, Attn: Gretchen Arentzen.

FOR FURTHER INFORMATION CONTACT: Gretchen Arentzen (Northwest Region, NMFS), phone: 206–526–6147, fax: 206–526–6736 and e-mail *gretchen.arentzen@noaa.gov;* or Becky Renko (Northwest Region, NMFS), phone: 206–526–6110 fax: 206–526–6736 and e-mail *becky.renko@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

This final rule is accessible via the Internet at the Office of the **Federal Register**'s Web site at *http://www.gpoaccess.gov/fr/index.html.* Background information and documents are available at the Pacific Fishery Management Council's (Council's) Web site at *http://www.pcouncil.org/.*

Background

The Pacific Coast Groundfish FMP and its implementing regulations at title 50 in the Code of Federal Regulations (CFR), part 660, subpart G, regulate fishing for over 90 species of groundfish off the coasts of Washington, Oregon, and California. Groundfish specifications and management measures are developed by the Council, and are implemented by NMFS. A proposed rulemaking to implement the 2007–2008 specifications and management measures for the Pacific Coast groundfish fishery and Amendment 16–4 of the FMP was published on September 29, 2006 (71 FR 57764). The final rule to implement the 2007–2008 specifications and management measures for the Pacific Coast Groundfish Fishery was published on December 29, 2006 (71 FR 78638). These specifications and management measures were codified in the CFR (50 CFR part 660, subpart G). The final rule was subsequently amended on March 20, 2007 via a correcting amendment (71 FR 13043).

Changes to current groundfish management measures implemented by this action were recommended by the Council, in consultation with Pacific Coast Treaty Indian Tribes and the States of Washington, Oregon, and California, at its March 5–9, 2007, meeting in Sacramento, California. The Council recommended changes to current regulations pertaining to two separate actions: (1) Setting the final 2007 ABC and OY values for the Pacific coast whiting fishery and the 2007 tribal

allocation of whiting; and (2) adjusting current groundfish management measures to respond to updated fishery information and other inseason management needs.

Pacific Whiting Specifications for 2007

In November 2003, the United States and Canada signed an agreement regarding the conservation, research, and catch sharing of whiting. The whiting catch sharing arrangement that was agreed upon provides 73.88 percent of the total catch OY to the U.S. fisheries and 26.12 percent to the Canadian fisheries. At this time, both countries are taking steps to fully implement this agreement. Until this occurs, the negotiators recommended that each country apply the agreed upon provisions to their respective fisheries.

In anticipation of the ratification of the U.S.-Canada agreement, a new stock assessment, and given the small amount of whiting that is typically landed under trip limits prior to the April 1 start of the primary season, the Council adopted a range for OY and ABC in the 2007–2008 specifications, and delayed adoption of final 2007 and 2008 ABC and OY until its March 2007 and 2008 meetings, respectively. To date, the international agreement has not yet been ratified by the United States, but the implementing legislation was recently signed into law on January 12, 2007. The ABC and OY values recommended by the Council as final ABC and OY values for 2007 are based on the 2007 stock assessment, and their impacts are within the scope of impacts considered in the EIS for the 2007 and 2008 management measures. The whiting OY being implemented in this rule, and the resulting allocations among the sectors, is reduced by approximately 10 percent from the 2006 OY.

Pacific Whiting Stock Status

In general, whiting is a very productive species with highly variable recruitment (the biomass of fish that mature and enter the population and/or fishery each year) and a relatively short life span when compared to other groundfish species. In 1987, the whiting biomass was at a historically high level due to an exceptionally large number of fish that recruited into the population in 1980 and 1984 (fish recruited during a particular year are referred to as year classes). As these large year classes of fish passed through the population and were replaced by moderate sized year classes, the stock declined. The whiting stock stabilized between 1995 and 1997, but then declined to its lowest level in 2001. After 2001, the whiting biomass increased substantially as a strong 1999 year class matured and entered the spawning population. The 1999 year class has now reached its peak biomass level and is declining, and in the absence of additional strong year classes the stock is expected to decline in the near term even in the absence of fishing.

The joint US-Canada Stock Assessment Review (STAR) panel met February 5–9, 2007, to review the whiting stock assessment prepared jointly by scientists from the NMFS Northwest Fisheries Science Center and the University of British Columbia Fisheries Centre. The STAR panel accepted two equally plausible assessment models that consider uncertainty in the relative depletion level and stock productivity.

As in 2006, the amount of whiting that the hydroacoustic survey was able to measure relative to the total amount of whiting in the surveyed area (acoustic survey catchability coefficient, or q) was identified as a major source of uncertainty in the new stock assessment. Because of this uncertainty, two models were presented to bracket the range of uncertainty in q: The base model with a fixed value of q=1, representing the lower range of biomass and ABC/OY estimates; and the alternative model (using an informative prior) to arrive at q=0.7, which results in an upward scaling of both biomass and ABC/OY estimates. Uncertainty regarding the true value of q has been a major issue with whiting stock assessments in recent years, and as a precautionary measure the Council has based whiting ABCs from the last several assessments on models where q=1.

Using the base model, q=1, the whiting stock biomass at the end of 2006 was estimated to be at 36 percent of its unfished biomass and at 44 percent of its unfished biomass with the alternative model, q=0.7. As no strong year classes have been observed since 1999, the whiting biomass is projected to decline in the near future. Data from the 2005 hydroacoustic survey suggested a moderately strong 2003 year class; however current recruitment estimates from fishery-dependent indices predict that the 2003 recruitment will be below the mean. Current estimates, while not validated with a hydroacoustic survey, predict larger 2004 recruitment than for surrounding years. If these year classes are stronger than currently projected, the recent downward trend in whiting biomass could stabilize.

The steepness of the stock-recruitment relationship (the proportion of young fish entering the population in relation to the number of adult fish) in the 2007 assessment was estimated to be 0.75. This is the same value that was used in 2006 when it was redefined in the 2006 assessment, whereas a value of 1 was used in 2005. Assuming a steepness of 1 implies that the spawning biomass level has no influence on the number of recruits produced in any given year, which may result in overly optimistic projections. Reducing the steepness to 0.75 increases the dependency of recruitment on the number of adult fish in the population. Based on its review, the SSC endorsed the use of both models in setting 2007 ABCs and OYS.

The U.S. implementing legislation and the U.S.-Canada agreement provisions include the use of a default harvest rate of F_{40}. A harvest rate of F_{40} can be explained as that which reduces spawning potential per female to 40 percent of what it would have been without fishing mortality. The selection of the F_{40} value was based on an analysis of stock and recruitment data for other whiting (hake) species. However, because the whiting stock is projected to fall below the overfished threshold if managed with a harvest rate of F_{40}, primarily due to the highly variable recruitment characteristic of the stock, the SSC noted that use of a control rule that allows for maximized yield may be inconsistent with the need to prevent whiting from falling below the overfished threshold.

The range of U.S. ABCs and OYs considered by the Council and analyzed in the EIS for 2007 and 2008 included: A low ABC of 244,425 mt and a high ABC of 733,275 mt (50 percent and 150 percent, respectively, of the 2006 U.S. ABC of 488,850); and a low OY of 134,534 mt and a high OY of 403,604 mt (50 percent and 150 percent, respectively, of the 2005/2006 U.S. OY of 269,069). These broad ranges in whiting harvest levels were analyzed in order to assess the potential range of the effects of the whiting fishery on incidentally-caught overfished species and the economic effects to coastal communities.

At its March 5–9, 2007, meeting in Sacramento, CA, the Council reviewed the results of the new whiting stock assessment and recommended adopting a U.S.-Canada coastwide ABC of 612,068 mt (results in a U.S. ABC of 452,196 mt) based on the q=1 assessment model. Because the whiting biomass is estimated to be below 40 percent of its unfished biomass, the 40–10 adjustment was applied as specified in the Pacific Coast Groundfish FMP, the U.S.-Canada agreement, and the Pacific Whiting Act of 2006. With the 40–10 adjustment, the U.S.-Canada

coastwide OY was 575,090 mt with the q=1 model, and 878,670 mt with the q=0.7 model. The potential OYs with the 40–10 adjustment were considered by the Council to be too high during a time when the stock biomass is in decline. The 40–10-based OY for the q=1 model was projected to result in the stock biomass falling below the overfished threshold of 25 percent of unfished biomass by 2008. The 40–10-based OY for the q=0.7 model was projected to result in the stock biomass falling below the overfished threshold by 2009. Given the potential impact on future stock biomass levels and as contemplated by the Pacific Whiting Act of 2006, the Council considered a more conservative range of U.S.-Canada coastwide OYs.

Following discussion and public testimony, the Council recommended adopting a U.S.-Canada coastwide OY of 328,358 mt, which corresponds to a U.S. OY of 242,591 mt according to the international allocation in the U.S.-Canada agreement. The 2007 U.S. OY is almost 10 percent less than the 2006 OY (269,069 mt), as a precautionary response to the declining trend in stock biomass, no strong year class available for the 2007 fishery, and continuing uncertainty in the model relative to the parameter q. With a constant harvest rate corresponding to the 2007 U.S. OY of 242,591 mt, the stock biomass level is projected to drop below the overfished level (B_{25}, or 25 percent of estimated unfished biomass) by 2009 if q=1 is the true state of nature; however, the biomass would remain near 30 percent of the unfished level through 2009 if q=0.7 is the true state of nature. When the results of both models are combined and given equal weighting, the 2009 depletion level is projected to be slightly above the overfished level. Because whiting stock assessments are prepared annually and OYs adjusted annually, the risk of reaching an overfished condition is reduced. A new stock assessment will be prepared prior to the 2008 fishing year and will provide an opportunity to further adjust harvest levels in response to new assessment information. The 2008 assessment will be informed with results from the 2007 hydroacoustic survey (the 2007 assessment used results from the 2005 hydroacoustic survey which is conducted every other year) and will further investigate the appropriateness of model parameters, harvest rates proxies, and year class strength.

Allocations

In 1994, the United States formally recognized that the four Washington coastal treaty Indian tribes (Makah, Quileute, Hoh, and Quinault) have treaty rights to fish for groundfish in the Pacific Ocean. In general terms, the quantification of those rights is 50 percent of the harvestable surplus of groundfish that pass through the tribes' usual and accustomed fishing areas (described at 50 CFR 660.324).

The Pacific Coast Indian treaty fishing rights, described at 50 CFR 660.324 and 660.385, provide for the allocation of groundfish to the tribes through the specifications and management measures process. A tribal allocation is subtracted from the species' OY before limited entry and open access allocations are derived. The tribal whiting fishery is a separate fishery, and is not governed by the limited entry or open access regulations or allocations. To date, only the Makah Tribe has participated. The Makah Tribe regulates, and in cooperation with NMFS, monitors this fishery so as not to exceed the tribal allocation.

Beginning in 1999, NMFS set the tribal allocation according to an abundance-based sliding scale method, proposed by the Makah Tribe in 1998 (see 64 FR 27928, May 24, 1999; 65 FR 221, January 4, 2000; and 66 FR 2338, January 11, 2001). Details on the abundance-based sliding scale allocation method and related litigation were discussed in the preamble to the proposed rule to implement the 2005–2006 groundfish specifications and management measures and are not repeated here. On December 28, 2004, the Ninth Circuit Court of Appeals upheld the sliding scale approach in *Midwater Trawler's Cooperative* v. *Daley,* 393 F. 3d 994 (9th Cir. 2004). Under the sliding scale allocation method, the tribal allocation varies with the U.S. whiting OY, ranging from a low of 14 percent (or less) of the U.S. OY when OY levels are above 250,000 mt, to a high of 17.5 percent of the U.S. OY when the OY level is at or below 145,000 mt. For 2007, using the sliding scale allocation method, the tribal allocation will be 32,500 mt. The Makah Tribe is the only Washington Coast tribe that requested a whiting allocation for 2007. The tribal fleet is comprised of five midwater trawlers who deliver to shoreside plants and to one at-sea mothership.

The 2007 commercial OY (non-tribal) for whiting is 208,091 mt. This is calculated by deducting the 32,500 mt tribal allocation and 2,000 mt for research catch and bycatch in non-groundfish fisheries from the 242,591 mt U.S. OY. Regulations at 50 CFR 660.323(a)(2) divide the commercial OY into separate allocations for the non-tribal catcher/processor, mothership, and shore-based sectors of the whiting fishery and the specific values are found in tables 1a and 2a to part 660 subpart G.

The catcher/processor sector is comprised of vessels that harvest and process whiting at sea (the fleet has typically been six to nine vessels annually since the formation of the Pacific Whiting Conservation Cooperative in 1997). The mothership sector is comprised of motherships and catcher vessels that harvest whiting for delivery to motherships that process the whiting at sea (typically three–six motherships operate in the fishery with one mothership also servicing the tribal fleet). Motherships are vessels that do not harvest, but process the whiting at sea. The shoreside sector is comprised of vessels that harvest whiting for delivery to shoreside processors (in recent years, the number of participating vessels has ranged from 29 to 37 vessels, some of which also service the non-tribal mothership sector). Each sector receives a portion of the non-tribal commercial OY, with the catcher/processors receiving 34 percent (70,751 mt), the mothership sector receiving 24 percent (49,942 mt), and the shoreside sector receiving 42 percent (87,398 mt), amounts that are roughly an 11% reduction from 2005 and 2006 levels.

It should also be noted that whiting is not the only fishery that these vessels depend on. Shoreside vessels typically participate in other fisheries, such as non-whiting groundfish, crab, and shrimp fisheries. Mothership and catcher-processor vessels typically participate in the Alaska pollock fishery.

All whiting caught in 2007 before the effective date of this action will be counted against the new 2007 OY. As in the past, the specification include fish caught in state ocean waters (0–3 nautical miles (nm) offshore) as well as fish caught in the EEZ (3–200 nm offshore).

Inseason Adjustments to Fishery Management Measures

The Pacific Coast Groundfish FMP and its implementing regulations at 50 CFR part 660, subpart G, provide for routine management measures to be used for inseason management of the Pacific coast groundfish fishery. The changes to current groundfish management measures implemented by this action were recommended by the Council, in consultation with Pacific Coast Treaty Indian Tribes and the States of Washington, Oregon, and California, at its March 5–9, 2007, meeting in Sacramento, CA. At that

meeting the Council recommended changes to management measures in response to three primary concerns: (1) Higher than expected canary rockfish bycatch rates in the non-whiting limited entry trawl fishery north of 40°10.00′ N. lat. based on newly-available scientific information; (2) higher than expected catch of petrale sole in the limited entry trawl fishery; and (3) the need for state and Federal groundfish regulations to conform in order to minimize confusion for the public. To address these concerns, the Council recommended the following revisions to groundfish management measures: (1) Close the areas shoreward of the trawl Rockfish Conservation Area (RCA) north of Cape Alava and between Capa Arago and Humbug Mountain beginning April 1; (2) adjust the shoreward boundary of the trawl RCA to a line approximating the 60-fm (110-m) contour between Leadbetter Point and the Oregon-Washington border from April 1 through October 31; (3) adjust the seaward boundary of the trawl RCA to a line approximating the 150-fm (274-m) contour north of Cascade Head and to a line approximating the 200-fm (366-m) contour south of Cascade Head beginning April 1 through August 31; (4) adjust the seaward boundary of the trawl RCA to the petrale-modified line approximating the 200-fm (366-m) contour, coastwide, from November 1 through December 31; (5) north of 40°10.00′ N. lat., increase cumulative limits for lingcod and shortspine thornyhead taken with large and small footrope trawl gear, and south of 40°10.00′ N. lat., increase cumulative limits for lingcod taken with large footrope and midwater trawl gear; (6) north of 40°10.00′ N. lat., decrease cumulative limits for selective flatfish trawls for sablefish, Dover sole, and petrale sole beginning May 1; (7) combine cumulative limited entry trawl limits for Other Flatfish and arrowtooth flounder coastwide beginning May 1; (8) north of 40°10.00′ N. lat., reduce cumulative limits for slope rockfish for all trawl gears beginning May 1; (9) reduce cumulative limits for petrale sole using large and small footrope trawl gears coastwide beginning May 1; and (10) adjust Federal regulations to conform with Washington recreational fishery management measures to prohibit the retention of groundfish seaward of a line approximating the 20-fm (37-m) contour from May 21 through September 30, in the area from the U.S. border with Canada to the Queets River, WA (47°31.70′ N. lat.), except on days when the Pacific halibut fishery is open in this area, and prohibit the retention of groundfish seaward of a line approximating the 30-fm (55-m) contour from March 17 through June 15, in the area between the Queets River and Leadbetter Point, except that retention of sablefish and Pacific cod is allowed from May 1 through June 15.

Overfished Species Bycatch Limits in the Pacific Whiting Fishery

The availability of overfished species as incidental catch, particularly canary rockfish, darkblotched rockfish, and widow rockfish, may prevent the industry from harvesting the entire whiting OY during 2007. To allow the industry to have the opportunity to harvest the higher whiting OY while keeping incidental catch within the rebuilding OYs for the incidental species, the Council recommended bycatch limits for the overfished species most commonly taken as incidental catch in the whiting fishery. With bycatch limits, the industry has the opportunity to harvest a larger amount of whiting, if they can do so while keeping the incidental catch of specific overfished species within adopted bycatch limits. Regulations provide for the automatic closure of the commercial (non-tribal) portion of the whiting fishery upon attainment of a bycatch limit.

In recent years, the most constraining overfished species for the whiting fishery have been darkblotched, canary and widow rockfish. Prior to this final rule, regulations at 50 CFR 660.373 (b)(4) contained the following bycatch limits for the commercial sectors (non-tribal) of the whiting fishery: 4.7 mt for canary, 200 mt for widow, and 25 mt for darkblotched rockfish.

At the March 2007 Council meeting, the Council's groundfish management team (GMT) examined the 2007 whiting OY alternatives in relation to the potential bycatch of overfished species. With a U.S. OY of 242,591 mt and in the absence of any further restrictions, the bycatch of canary rockfish was projected to be approximately 3.9 mt, the bycatch of widow rockfish was projected to be approximately 217 mt, and the bycatch of darkblotched rockfish was projected to be approximately 12.4 mt. After considering the projected catch of overfished species in all other fishing and research activities, the Council recommended that the canary and darkblotched rockfish bycatch limits for the whiting fishery remain at 4.7 mt and 25 mt, respectively, which were the same limits that were available during the 2006 primary whiting season. To accommodate current incidental catch projections for the non-tribal whiting fishery, the Council recommended the widow rockfish bycatch limit be raised to 220 mt, the same bycatch limit that was in effect at the end of 2006. With this increase, the 2007 estimated total catch of widow rockfish is still predicted to be well below the 2007 widow rockfish OY of 368 mt.

Limited Entry Trawl Fishery Management Measures

At its March 2007 meeting, the Council received new data and analyses on the catch of groundfish in the limited entry trawl fishery. The Council's recommendations for revising 2007 trawl fishery management measures focused on modifying the RCA boundary lines and trip limits to move vessels away from areas where canary rockfish most commonly co-occur with more abundant groundfish stocks, limiting the resulting effects of the movement of the fleet on darkblotched rockfish, and reducing the availability of petrale sole early in 2007 in order to better ensure that petrale sole is available for harvest later in the 2007 fishing year.

According to the most recently available West Coast Groundfish Observer Program (WCGOP) data, released in late January, 2007, bycatch rates for canary rockfish using selective flatfish trawl gear north of 40°10.00′ N. lat. were much higher in 2005 than had been anticipated. By applying these new bycatch rates to landings of target species in the existing fishery bycatch model, NMFS concluded that the 2005 canary rockfish OY had been exceeded by 2 mt. While estimated 2006 total catch of canary rockfish has yet to be determined, higher than anticipated bycatch rates in the north by selective flatfish trawls would be expected to continue in 2006. Based on 2005 WCGOP data indicating higher canary rockfish bycatch rates using selective flatfish trawls north of 40°10.00′ N. lat., NMFS believes that the canary rockfish OY could be exceeded in 2007 under status quo regulations. The 2007 regulatory measures were developed assuming a canary rockfish bycatch rate that now has been determined to be too low, which results in an underestimate in the predicted impacts to canary rockfish. In order to keep catch levels within the canary rockfish OY, inseason adjustments are necessary to constrain incidental canary rockfish catch in the limited entry non-whiting trawl fishery.

The Council considered several short term options available to reduce impacts on canary rockfish in the non-whiting limited entry trawl fishery north of 40°10.00′ N. lat. to harvest levels initially projected for the fisheries during development of the 2007

management measures: (1) The modification of trawl cumulative limits; (2) modifications of the trawl RCA boundaries; and (3) the use of management area boundaries and commonly used geographic coordinates, defined at 50 CFR 660.302 under ''North-South management area'', to provide more area-specific management measures on portions of the coast with differential canary rockfish bycatch rates. For the longer term, the Council discussed the development of other tools, such as more refined area closures, similar to the yelloweye rockfish RCAs, but concluded that implementing these types of closures would not be routine management measure changes under either the FMP at 6.2.D or Federal regulations at 50 CFR 660.370(c).

Based on analysis of 2005 WCGOP data, the areas of the coast with highest bycatch rate of canary rockfish relative to target species taken in the non-whiting trawl fishery are: The area shoreward of the trawl RCA north of Cape Alava (48°10.00′ N. lat.) to the U.S./Canada boundary; the area shoreward of the trawl RCA between Leadbetter Point (46°38.17′ N. lat.) and the Oregon/Washington border (46°16.00′ N. lat.); and the area shoreward of the trawl RCA between Cape Arago (43°20.83′ N. lat.) and Humbug Mountain (42°40.50′ N. lat.). The Council considered several combinations of available management measures and looked at the projected impact of these measures on the resource and the fishery. In order to keep projected impacts of the non-whiting trawl fishery on canary rockfish within the 2007 OY, and to allow fishing opportunities in geographic areas with low canary rockfish bycatch, several modifications were recommended to the limited entry non-whiting trawl fishery regulations, including: (1) Modify the trawl RCA boundaries; (2) close two areas of the coast shoreward of the trawl RCA; (3) reduce cumulative limits for some species using selective flatfish trawl gear; (4) combine arrowtooth and Other Flatfish into a flatfish species group with a single, reduced cumulative limit; and (5) increase opportunities for lingcod and shortspine thornyheads in areas seaward of the trawl RCA.

Rockfish Conservation Area Boundaries

The Council determined that, in order to constrain the incidental catch of canary rockfish and to prevent exceeding the 2007 canary rockfish OY, the limited entry trawl RCA north of 40°10.00′ N. lat. should be expanded shoreward, so that the RCA's shoreward boundary is no deeper than a line approximating the 75-fm (137-m) contour for the entire year. This RCA expansion is expected to have a dual effect of eliminating fishing opportunity in areas with trawl efforts exhibiting higher canary rockfish bycatch rates, as well as shifting fishing effort to areas exhibiting relatively lower canary rockfish bycatch rates. The Council also considered a more refined modification of the shoreward RCA boundaries in areas north of 40°10.00′ N. lat. that would close or substantially restrict areas with the highest bycatch rates, as identified from WCGOP data. The areas of highest canary rockfish bycatch rates included: The area shoreward of the RCA north of Cape Alava; the area shoreward of the RCA between Leadbetter Point and the Washington/Oregon border; and the area shoreward of the RCA between Cape Arago and Humbug Mountain. The Council's Groundfish Management Team (GMT) analyzed the effect of relatively greater restrictions in these three areas and, based on that analysis, recommended closing the shoreward area north of Cape Alava, closing the shoreward area between Cape Arago and Humbug Mountain, and expanding the shoreward boundary of the trawl RCA to a line approximating the 60-fm (110-m) contour during the summer in the area between Leadbetter Point and the Oregon/Washington border. The Council also considered various alternatives that would leave the area shoreward of the RCA and north of Cape Alava open during winter months to reduce the disproportionate impact this closure would have on vessels based in northern Washington. However, the necessary reductions in cumulative trip limits required to keep this area open would make trawling with selective flatfish gear not economically viable for many participants in the non-whiting trawl fishery. The Council also considered the potential impacts of interaction with soft-shelled crab as trawl effort is shifted to areas closer to shore between Leadbetter Point and the Oregon/Washington border during summer months. The line approximating the 60-fm (110-m) depth contour is farther offshore in this area and GMT analysis suggested that interactions between groundfish trawlers and soft-shelled crab would be minimal if a 60-fm (110-m) shoreward boundary were put in place. In order to reduce economic impacts on vessels that formerly operated in the nearshore fishing areas, the Council supported liberalization, where possible, of the seaward boundary of the RCA in order to provide open fishing areas of relatively low canary bycatch to accommodate a shift in fishing effort from nearshore to offshore waters. The benefits of shifting effort offshore are twofold: Since the highest rates of canary bycatch occur in the areas shoreward of the RCA, shifting effort seaward of the RCA further reduces the effort in the nearshore areas that remain open, thus reducing the amount of canary rockfish caught in those areas; and some displaced vessels whose effort was concentrated in the areas that are now closed may be able to shift their effort seaward of the RCA and remain in the fishery.

Trawl fishing opportunities seaward of the trawl RCA are primarily constrained by measures intended to minimize the incidental catch of darkblotched rockfish. Data from the NMFS trawl survey, logbook data, and anecdotal information from the trawl industry shows that various target species and darkblotched rockfish are found in shallower depths in the north and move deeper toward the south. The Council considered changes to the seaward boundary of the RCA within the context of allowing increased fishing opportunity while maintaining protections for darkblotched rockfish. Dividing the seaward boundary of the RCA at Cascade Head (45°03.83′ N. lat.) allows more refined area management in response to the depth-based shift in abundance from north to south of darkblotched rockfish and target species. North of Cascade Head, target species and darkblotched rockfish are more abundant in shallower water, so the seaward boundary of the RCA can be shifted shoreward to allow increased targeting opportunity while still protecting darkblotched rockfish. South of Cascade Head, target species and darkblotched rockfish are more abundant in deeper water, so only minor adjustments to the seaward boundary of the RCA, which remains similar to what was in place at the beginning of 2007, provides targeting opportunity while still protecting darkblotched rockfish.

Based on the information and analysis described above, the Council recommended and NMFS is implementing the following changes to the trawl RCA north of 40°10.00′ N. lat.: North of Cape Alava, and between Cape Arago and Humbug Mountain, the shoreward boundary of the RCA is shifted to the shore, closing the area shoreward of the RCA for the remainder of 2007; between Leadbetter Point and the Oregon/Washington border, the shoreward boundary is shifted

shoreward to a line approximating the 60-fm (110-m) depth contour from April 1 through October 31; unless otherwise specified above, the RCA will have a shoreward boundary of a line approximating the 75-fm (137-m) depth contour from April 1 through December 31, 2007; north of Cascade Head, the seaward boundary of the trawl RCA is shifted shoreward to a line approximating the 150-fm (274-m) depth contour from April 1 through August 31, 2007; north of Cascade Head, the seaward boundary of the RCA will remain at a line approximating the 200-fm (366-m) depth contour from September 1 through October 31, 2007; south of Cascade Head, the seaward boundary of the RCA will be shifted shoreward to a line approximating the 200-fm (366-m) depth contour from April 1 through April 30, and remain at the 200-fm (366-m) depth contour through October 31, 2007; north of 40°10.00′ N. lat., the seaward boundary of the RCA will be shifted shoreward to a line approximating the petrale-modified 200-fm (366-m) depth contour from November 1 through December 31, 2007.

Limited Entry Trawl Trip Limits

In addition to area closures, the Council determined that cumulative limits in the limited entry trawl fishery north of 40°10.00′ N. lat. should be modified to: Reduce effort and catch of target species in order to reduce impacts on co-occurring canary rockfish and prevent exceeding the 2007 canary rockfish OY; constrain the effect of any fleet movement away from canary rockfish grounds and into darkblotched rockfish grounds; and reduce the early 2007 rate of petrale sole catch in order to allow more petrale sole to be available for harvest later in the 2007 season.

The Council considered various combinations of cumulative limit adjustments paired with RCA modifications and area closures to reduce impacts to canary rockfish. As with the RCA boundary revisions, the Council's GMT analyzed revisions to trip limits intended to shift fishing effort away from areas where canary rockfish are more commonly taken as bycatch. The GMT recommended that the Council consider reducing sablefish and Dover sole opportunity for vessels using selective flatfish trawl gear, in order to provide for a disincentive to fish in areas where canary rockfish are found and to shift effort away from areas with a relatively high canary rockfish bycatch rate. Reductions in petrale sole opportunities were primarily driven by the need to slow the catch of petrale sole, but this adjustment also results in lower impacts on canary rockfish compared to status quo measures.

Given the need to reduce overall catch and to result in lower predicted canary rockfish impacts than under current management measures, the GMT also recommended combining the arrowtooth and Other Flatfish cumulative limits to enable fishermen to better vary their target strategy while still gaining the benefit of reducing canary rockfish impacts. GMT estimates showed that this approach allows for greater opportunities for those particular target strategies, but that the total catch, and thus overfished species impacts, are less than if separate cumulative limits were applied.

Based on these analyses and recommendations the Council recommended and NMFS is implementing a decrease in the limited entry selective flatfish trawl fishery cumulative limits north of 40°10.00′ N. lat. beginning May 1: For sablefish from ''8,000 lb per two months'' to ''5,000 lb per two months'' through December 31, 2007; for Dover sole from ''40,000 lb per two months'' to ''38,000 lb per two months'' through October 31, 2007 and from ''40,000 lb per two months'' to ''25,000 lb per two months'' through December 31, 2007; and for petrale sole, from ''25,000 lb per two months'' to ''20,000 lb per two months'' through August 31, 2007, to ''15,000 lb per two months'' from September 1 through October 31, and to ''8,000 lb per two months'' from November 1 through December 31, 2007. The Council also recommended and NMFS is implementing, beginning May 1, combining cumulative limits for arrowtooth and Other Flatfish within a single cumulative limit for Other Flatfish (including arrowtooth). For large and small footrope trawl gears, arrowtooth limits are modified from ''100,000 lb per two months'' and combined within Other Flatfish limits into a combined cumulative limit of ''110,000 lb per two months'' through December 31, 2007. For selective flatfish trawl gears, arrowtooth limits are modified from ''90,000 lb per two months'' and combined within Other Flatfish limits into a combined cumulative limit of ''70,000 lb per two months'' through October 31, 2007. Beginning November 1, the cumulative limit for Other Flatfish, including arrowtooth, taken with selective flatfish trawl gear is reduced from ''90,000 lb per two months'' to ''30,000 lb per two months'' through December 31, 2007.

In addition to liberalizing the seaward boundaries of the trawl RCA north of 40°10.00′ N. lat., the Council considered increasing cumulative limits for DTS species and lingcod in areas seaward of the RCA in order to shift more fishing effort to offshore waters. North of 40°10.00′ N. lat., the Council considered increasing limits for lingcod and shortspine thornyheads taken with large and small footrope trawl gears, which are only allowed when fishing seaward of the trawl RCA, to create incentives to fish in areas with lower canary rockfish bycatch rates. South of 40°10.00′ N. lat., the Council considered increasing limits for lingcod taken with large footrope and midwater trawl gears, which are only allowed when fishing seaward of the trawl RCA, to accommodate a shift in effort from shoreward areas, and to reduce discards of non-constraining target species. The Council determined that increasing trip limits for lingcod and shortspine thornyhead would help prevent exceeding the 2007 canary rockfish OY, reduce unnecessary discards, and reduce economic impacts for the following reasons: (1) The shift in effort to areas with lower canary rockfish bycatch rates will reduce total coastwide incidental catch of canary rockfish; (2) it may reduce the economic impacts on vessels displaced by nearshore fishery closures by providing fishing opportunity while also constraining incidental catch of canary rockfish; and (3) it will reduce unnecessary discards of lingcod and shortspine thornyheads.

Increasing incentives to fish seaward of the trawl RCA will increase effort in an area of known darkblotched rockfish abundance; accordingly, the Council considered various ways to mitigate these impacts and prevent exceeding the 2007 darkblotched rockfish OY.

Changes to management measures to constrain the catch of canary rockfish will also affect the incidental catch of darkblotched rockfish and Pacific ocean perch (POP). The incidental catch of darkblotched rockfish is likely to increase compared to predicted impacts under current management measures, and will be caused by a shift in effort away from areas of high canary rockfish bycatch to areas of greater darkblotched rockfish and POP abundance. However, POP is not considered to be a constraining species in the limited entry trawl fishery; the inseason adjustments to management measures implemented by this action are anticipated to keep POP total catch well within its 2007 OY of 150 mt. The Council focused its discussions of various continental slope actions to prevent exceeding the 2007 darkblotched rockfish OY, including modification of the seaward boundary of the trawl RCA, and changes in catch limit opportunities. The Council's GMT

analyzed the effects of changes in RCA boundaries, cumulative limit opportunities, and fishing effort on the incidental catch of darkblotched rockfish, and recommended that cumulative limits for slope rockfish be decreased to reduce the impact of greater effort occurring in areas where darkblotched rockfish are found. The combined effects of these actions are predicted to result in a total 2007 catch of darkblotched rockfish that is lower than the 2007 OY. Catch of darkblotched rockfish will be monitored and action can be taken inseason if necessary to modify the trawl RCA and cumulative limits to keep total catch within the 2007 darkblotched rockfish OY.

Based on these analyses and recommendations, the Council recommended and NMFS is implementing an increase in the limited entry trawl fishery cumulative limits taken with large and small footrope trawl gears north of 40°10.00′ N. lat. beginning May 1 through December 31, 2007: For lingcod from ''1,200 lb per two months'' to ''4,000 lb per two months''; and for shortspine thornyheads from ''7,500 lb per two months'' to ''10,000 lb per two months''. South of 40°10.00′ N. lat., limited entry trawl fishery cumulative limits for lingcod taken with large footrope and midwater trawl gears will increase, beginning May 1 through December 31, 2007, from ''1,200 lb per two months'' to ''4,000 lb per two months''. The Council also recommended and NMFS is implementing a decrease in the limited entry trawl fishery cumulative limits for minor slope and darkblotched rockfish north of 40°10.00′ N. lat., beginning May 1 through December 31, 2007, from ''4,000 lb per two months'' to ''1,500 lb per two months''.

In early February 2007, NMFS received preliminary fishery data showing higher than expected limited entry trawl landings of petrale sole. NMFS estimated that the catch of petrale sole could be 1,200 mt out of a coastwide OY of 2,499 by the end of February. On February 9, NMFS issued a public notice asking for industry cooperation in reducing petrale sole catch to keep petrale sole from exceeding the 2007 OY, and still allow for management flexibility to keep petrale sole fishing opportunities throughout the calendar year. As a result of this voluntary action, significant reductions in catch occurred during the remainder of February and petrale sole catch was estimated to be between 850 and 900 mt at the end of February. In an effort to slow the catch of petrale sole, to prevent exceeding the 2007 OY, and allow petrale sole target opportunities through the end of 2007, the Council considered reductions of petrale sole cumulative limits in the limited entry trawl fishery. Industry representatives indicated that petrale sole limits less than 20,000 lbs (9,072 kg) per two months were not economically sustainable, given the cost of fuel needed to access that catch. The Council also considered the effects of petrale sole cumulative limit reductions on the bycatch of canary rockfish.

Based on these analyses and information, the Council recommended and NMFS is implementing a decrease in the limited entry trawl fishery cumulative limits for petrale sole north of 40°10.00′ N. lat.: Beginning May 1 through October 31, 2007, from ''25,000 lb per two months'' to ''20,000 lb per two months''; and beginning November 1 through December 31, 2007, from ''50,000 lb per two months'' to ''30,000 lb per two months''. South of 40°10.00′ N. lat., beginning May 1 through October 31, 2007, the Council recommended and NMFS is implementing reductions in cumulative limits for petrale sole from ''30,000 lb per two months'' to ''25,000 lb per two months''.

Washington's Recreational Groundfish RCA

The States of Washington and Oregon manage canary and yelloweye rockfish under a joint harvest guideline for their recreational fisheries. The states modify portions of their recreational fisheries, through inseason adjustment to state regulations, in order to keep catch within the harvest guidelines for canary and/or yelloweye rockfish.

During 2005, after receiving inseason recreational catch data, the Washington Department of Fish and Wildlife's (WDFW) revised catch projections for the year indicated that the state harvest targets for canary and yelloweye rockfish would be prematurely attained, and WDFW took action to prevent exceeding the Washington/Oregon harvest guidelines for these species. For 2006, new Washington recreational management measures were adopted to avoid early canary and yelloweye rockfish harvest guideline attainment. During development of the 2007–2008 groundfish specifications and management measures, WDFW identified additional RCA restrictions that could be in place if needed, based on harvest data through 2005. These additional restrictions were adopted by the Council and implemented by NMFS in the final rule for the 2007–2008 groundfish specifications and management measures (71 FR 78638). New 2006 harvest estimates, based on data collected in WDFW's Ocean Sampling Program, indicated that the Washington recreational fishery stayed well below their portion of the 2006 Oregon/Washington harvest guidelines, harvesting 1.28 mt of canary and 1.70 mt of yelloweye (out of the 2006 Oregon/Washington harvest guidelines of 8.5 mt and 6.7 mt for canary and yelloweye rockfish, respectively). The 2007 Oregon/Washington canary and yelloweye rockfish harvest guidelines are 8.2 mt and 6.8 mt, respectively. At the March 2007 meeting, WDFW requested that the duration of the closure of the Washington recreational RCAs be shortened for 2007 and 2008 to reduce the adverse impacts on Washington's coastal communities from the additional restrictions implemented as part of the 2007–2008 specifications and management measures. Compared to the duration of the Washington recreational RCAs implemented in the 2007–2008 specifications, the 2007–2008 closure north of Queets River will be 20 days shorter and between the Queets River and Leadbetter Point, the 2007–2008 closure will be 46 days shorter. Based on data from the 2006 Washington recreational fisheries, the revised RCA restrictions are still expected to constrain total catch of canary and yelloweye rockfish to stay within the shared Oregon and Washington harvest guidelines.

Therefore, the Pacific Council recommended and NMFS is implementing: (1) A prohibition of groundfish fishing in the Washington recreational fishery, north of the Queets River and seaward of a line approximating the 20-fm (37-m) contour from May 21–September 30, except on days when the Pacific halibut fishery is open in this area; and (2) a prohibition of groundfish fishing in the Washington recreational fishery, between the Queets River and Leadbetter Point seaward of a line approximating the 30–fm (55-m) contour from March 17–June 15, except retention of sablefish and Pacific cod is allowed from May 1–June 15.

Classification

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

Final Whiting Specifications for 2007 and Inseason Adjustments to Fishery Management Measures

The final whiting specifications and management measures for 2007 are issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and are in

accordance with 50 CFR part 660, the regulations implementing the FMP. These actions are based on the most recent data available. The aggregate data upon which these actions are based are available for public inspection at the Office of the Administrator, Northwest Region, NMFS, (see **ADDRESSES**) during business hours.

For the following reasons, NMFS finds good cause to waive prior public notice and comment on the revisions to the 2007 Pacific whiting specifications under 5 U.S.C. 553(b)(B) because notice and comment would be impracticable and contrary to the public interest. Also for the same reasons, NMFS finds good cause to waive the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d)(3), so that this final rule may become effective as close as possible to the April 1, 2007, fishery start date.

The proposed rulemaking to implement the 2007 specifications and management measures, published on September 29, 2006 (71 FR 57764), first explained the need to delay adopting the whiting ABC and harvest specifications until after the March 2007 and March 2008 Council meetings. NMFS requested public comment on the proposed rule through October 31, 2006. The final rule, published on December 29, 2006 (71 FR 78638), again explained the range in the specifications and that the final OY and ABC would be recommended at the Council's March 2007 and 2008 meetings.

The FMP requires that fishery specifications be evaluated periodically using the best scientific information available. Every year NMFS does a stock assessment in which U.S. and Canadian scientists cooperate. The 2007 stock assessment for whiting was prepared in early 2007, the earliest possible time to conduct an assessment incorporating 2006 data. Whiting differs from other groundfish species in that it has a shorter life span and the population exhibits greater recruitment variability. Thus, it is important to use the most recent fisheries and survey data in stock assessment when determining ABC and OY. Because of the timing of the assessment, the results are not available for use in developing the new ABC and OY until just before the Council's annual March meeting. The Council made its recommendations at its March 5–9, 2007 meeting in Sacramento, CA.

For the actions to be implemented in this final rule, affording the time necessary for prior notice and opportunity for public comment would prevent the Agency from managing the Pacific whiting and related fisheries using the best available science by approaching without exceeding the OYs for federally managed species. The adjustments to management measures in this document affect commercial trawl fisheries off Washington, Oregon, and California and recreational fisheries off Washington. These adjustments to management measures must be implemented immediately to: Prevent exceeding the 2007 OYs for petrale sole, widow rockfish, and canary rockfish; prevent premature closure of fisheries; and eliminate confusion for the public and to improve enforcement by ensuring that Federal and state recreational regulations conform to each other.

Changes to the cumulative limits in the limited entry trawl fishery and to the trawl RCA are needed to reduce the projected bycatch of canary rockfish, a groundfish species that is currently subject to rebuilding requirements. The projected bycatch of canary rockfish must be reduced in order to keep coastwide fisheries from exceeding that species's rebuilding OY. Changes to the trawl RCA to reduce the bycatch of canary rockfish must be implemented as close as possible to the April 1, 2007 start of the fishing season so that the total catch of canary rockfish stays within its 2007 OY, as defined in the rebuilding plan for this species. Changes to petrale sole cumulative limits in the limited entry trawl fishery must be implemented in a timely manner by May 1, 2007, so that harvest of petrale sole stays within the harvest levels projected for 2007 and so that petrale sole catch is available for harvest for as long as possible throughout the year.

Changes to the non-tribal whiting widow rockfish bycatch limit must be implemented as close as possible to the start of the California whiting fishery, on April 1, 2007. Ensuring that the bycatch limit is in place by the season start date provides an opportunity for participants in this fishery to catch the available whiting quota without reaching or exceeding the bycatch limit of widow rockfish or its OY, prematurely closing the fishery.

Changes to the Washington recreational groundfish RCA must be implemented in a timely manner by May 1, 2007, to allow the recreational fishermen to fish in the newly opened area in the EEZ, in order to eliminate confusion for the public, and to improve enforcement by ensuring that Federal and state recreational regulations conform to each other.

These revisions are needed to protect overfished groundfish species and to keep the harvest of other groundfish species within the harvest levels projected for 2007, while allowing fishermen access to healthy stocks. Without these measures in place, the fisheries could risk exceeding harvest levels early in the year, causing early and unanticipated fishery closures and economic harm to fishing communities. Delaying these changes would keep management measures in place that are not based on the best available data and which could lead to early closures of the fishery if harvest of groundfish exceeds levels projected for 2007. Such delay would impair achievement of one of the Pacific Coast Groundfish FMP objectives of providing for year-round harvest opportunities or extending fishing opportunities as long as practicable during the fishing year. In addition, it is also in the public interest to implement the recreational measures in this notice as soon as possible to improve enforcement and eliminate confusion for the public by removing differences between different regulations that affect the same waters and fisheries.

The environmental impacts associated with the Pacific whiting harvest levels being adopted by this action are considered in the final environmental impact statement for the 2007–2008 specifications and management measures. Copies of the FEIS and the ROD are available from the Council (*see* **ADDRESSES**).

Pursuant to Executive Order 13175, this action was developed after meaningful consultation and collaboration with tribal officials from the area covered by the FMP. Under the Magnuson-Stevens Act at 16 U.S.C. 1852(b)(5), one of the voting members of the Council must be a representative of an Indian tribe with federally recognized fishing rights from the area of the Council's jurisdiction. In addition, regulations implementing the FMP establish a procedure by which the tribes with treaty fishing rights in the area covered by the FMP request new allocations or regulations specific to the tribes, in writing, before the first of the two meetings at which the Council considers groundfish management measures. Only the Makah Tribe requested a whiting allocation for 2007. The regulations at 50 CFR 660.324(d) further state ''the Secretary will develop tribal allocations and regulations under this paragraph in consultation with the affected tribe(s) and, insofar as possible, with tribal consensus.'' The tribal whiting allocation finalized by this final rule was recommended by the Council based on the sliding scale allocation formula described above.

List of Subjects in 50 CFR Part 660

Fishing, Fisheries, and Indian fisheries.

Dated: April 11, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

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

■ 2. In § 660.373, paragraph (b)(4) is revised to read as follows:

§ 660.373 Pacific whiting (whiting) fishery management.

* * * * *

(b) * * *

(4) *Bycatch limits in the whiting fishery.* The bycatch limits for the whiting fishery may be used in season to close a sector or sectors of the whiting fishery to achieve the rebuilding of an overfished or depleted stock, under routine management measure authority at § 660.370(c)(1)(ii). These limits are routine management measures under § 660.370(c) and, as such, may be adjusted inseason or may have new species added to the list of those with bycatch limits. The whiting fishery bycatch limits for the sectors identified in § 660.323(a) are: 4.7 mt of canary rockfish; 220 mt of widow rockfish; and 25 mt of darkblotched rockfish.

* * * * *

■ 3. In § 660.384, paragraphs (c)(1)(i)(C)(*1*) and (*2*) are revised to read as follows:

§ 660.384 Recreational fishery management measures.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(C) * * *

(*1*) Between the U.S. border with Canada and the Queets River, recreational fishing for groundfish is prohibited seaward of a boundary line approximating the 20-fm (37-m) depth contour from May 21 through September 30, except on days when the Pacific halibut fishery is open in this area. Days open to Pacific halibut recreational fishing off Washington are announced on the NMFS hotline at (206) 526–6667 or (800) 662–9825. Coordinates for the boundary line approximating the 20-fm (37-m) depth contour are listed in § 660.391.

(*2*) Between the Queets River and Leadbetter Point, recreational fishing for groundfish is prohibited seaward of a boundary line approximating the 30-fm (55-m) depth contour from March 17, 2007, through June 15, 2007, except that recreational fishing for sablefish and Pacific cod is permitted within the recreational RCA from May 1 through June 15. In 2008, recreational fishing for groundfish is prohibited seaward of a boundary line approximating the 30-fm (55-m) depth contour in from March 15, 2008, through June 15, 2008, except that recreational fishing for sablefish and Pacific cod is permitted within the recreational RCA from May 1 through June 15. Coordinates for the boundary line approximating the 30-fm (55-m) depth contour are listed in § 660.391.

* * * * *

■ 4. Table 1a to part 660 subpart G is revised to read as follows.

BILLING CODE 3510–22–P

Table 1a. To Part 660, Subpart G - 2007 Specifications of Acceptable Biological Catch (ABC), Optimum Yields (OYs), Harvest Guidelines (HGs) by Management Area (weights in metric tons).

Species	ABC Specifications						OY b/	HG b/	
	ABC Contributions by Area					ABC		Commercial	Recreational
	Vancouver a/	Columbia	Eureka	Monterey	Conception				
ROUNDFISH:									
Lingcod c/ north of 42° N. lat.	5,428		852			6,280	5,558		
south of 42° N. lat.							612		
Pacific Cod e/	3,200		d/			3,200	1,600	1,200	
Pacific Whiting f/	452,196					452,196	242,591		
Sablefish g/	6,210					6,210	5,934	5,362	
Cabezon h/ south of 42° N. lat.	d/		71		23	94	69	27	
FLATFISH:									
Dover sole i/	28,522					28,522	16,500		
English sole j/	6,237					6,237	6,237		
Petrale sole k/	1,397		1,628			3,025	2,499		
Arrowtooth flounder l/	5,800					5,800	5,800		
Starry Flounder m/	1,221					1,221	890		
Other flatfish n/	6,731					6,731	4,884		
ROCKFISH:									
Pacific Ocean Perch o/	900					900	150	111.3	
Shortbelly p/	13,900					13,900	13,900		
Widow q/	5,334					5,334	368	251.4	9.4
Canary r/	172					172	44	23.8	17.2
Chilipepper s/	d/			2,700		2,700	2,000		
Bocaccio t/	d/			602		602	218	80.2	66.3
Splitnose u/	d/			615		615	461		
Yellowtail v/	4,548			d/		4,548	4,548		

Table 1a. To Part 660, Subpart G - 2007 Specifications of ABCs, OYs, HGs by Management Area (weights in metric tons). - Continued

Species	ABC Specifications						OY b/	HG b/	
	ABC Contributions by Area					ABC			
	Vancouver a/	Columbia	Eureka	Monterey	Conception			Commercial	Recreational
ROCKFISH:									
Shortspine thornyhead w/ north of 34°27' N. lat.	2,476					2,476	1,634		
south of 34°27' N. lat.							421		
Longspine thornyhead x/ north of 34°27' N. lat.	3,907					3,907	2,220		
south of 34°27' N. lat.							476		
Cowcod y/ 36° to 40° 30 N. lat.	d/			19	--	19	4	3.1	0.3
south of 36° N. lat.	d/			--	17	17			
Darkblotched z/	456					456	290	259.8	
Yelloweye aa/	26					26	23	7.9	8.9
California Scorpionfish bb/					219	219	175	34	
Black cc/ north of 46°16' N. lat.	540					540	540		
south of 46°16' N. lat.			722			722	722		
Minor Rockfish dd/ north of 40° 10' N. lat.	3,680			--		3,680	2,270	2,181	89
Minor Rockfish ee/ south of 40° 10' N. lat.	--			3,403		3,403	1,904	1,418	486
Remaining Rockfish	1,612			1,105		--			
bank ff/	d/			350					
blackgill gg/	d/			292					
bocaccio north	318			--					
chilipepper north	32			--					
redstripe	576			d/					
sharpchin	307			45					
silvergrey	38			d/					

Table 1a. To Part 660, Subpart G - 2007 Specifications of ABCs, OYs, and HGs by Management Area (weights in metric tons). - Continued

Species	ABC Specifications						OY b/	HG b/	
	ABC Contributions by Area					ABC		Commercial	Recreational
	Vancouver a/	Columbia	Eureka	Monterey	Conception				
splitnose north	242			--					
yellowmouth	99			d/					
yellowtail south	--			116					
Gopher	d/			302					
Other rockfish hh/	2,068			2,298		--			
SHARKS/SKATES/RATFISH/MORIDS/GRENADIERS/KELP GREENLING:									
Other fish ii/	2,500	7,000	1,200	3,900		14,600	7,300		

a/ ABCs apply to the U.S. portion of the Vancouver area.

b/ Optimum Yields (OYs) and Harvest Guidelines (HGs) are specified as total catch values. Though presented as harvest guidelines, the recreational values for widow rockfish, bocaccio, and cowcod are catch estimates. A harvest guideline is a specified harvest target and not a quota. The use of this term may differ from the use of similar terms in state regulation.

c/ Lingcod- A coastwide lingcod stock assessment was prepared in 2005. The lingcod biomass was estimated to be at 64 percent of its unfished biomass in 2005. The ABC was calculated using an F_{MSY} proxy of $F_{45\%}$. The ABC of 6,280 mt is a two year average ABC for 2007 and 2008. Because the stock is above $B_{40\%}$ coastwide, the OY could be set equal to the ABC. Separate OYs are being adopted for the area north of 42° N. lat. and the area south of 42° N. lat. For that portion of the stock north of 42° N. lat. the OY of 5,558 mt is set equal to the ABC contribution for the area. The biomass in the area south of 42° N. lat. is estimated to be at 24 percent of the unfished biomass. As a precautionary measure, the OY for the southern portion of the stock is being set at 612 mt, which is lower than the ABC contribution for the area. An OY of 612 mt (equivalent to the 2006 OY) is expected to result in a biomass increase for the southern portion of the stock. The tribes do not have a specific allocation at this time, but are expected to take 30 mt of the commercial HG.

d/ "Other species", these species are neither common nor important to the commercial and recreational fisheries in the areas footnoted. Accordingly, these species are included in the harvest guidelines of "other fish", "other rockfish" or "remaining rockfish".

e/ Pacific Cod - The 3,200 mt ABC for the Vancouver-Columbia area is based on historical landings data. The 1,600 mt OY is the ABC reduced by 50 percent as a precautionary adjustment. A tribal harvest guideline of 400 mt is deducted from the OY resulting in a commercial OY of 1,200 mt.

f/ Pacific whiting - The most recent stock assessment was prepared in February 2007, and the whiting biomass was estimated to be between 36 percent and 44 percent of its unfished biomass at the end of 2006 using the base model with catchability coefficient of q=1 and q=0.7, respectively. Model estimates applying the 40-10 harvest policy rule resulted in ABCs and OYs that were unsupportably high. The U.S.-Canada coastwide ABC of 612,068 mt is based on the q=1 assessment model. Per the U.S.-Canada agreement, the U.S. portion of the coastwide ABC is 73.88 percent, resulting in a U.S. ABC of 452,196 mt. The U.S.-Canada coastwide OY of 328,358 mt is based on the 2006 coastwide OY, with a 10 percent precautionary reduction. Per the U.S.-Canada agreement, the U.S. portion of the

coastwide OY is 73.88 percent, resulting in a U.S. OY of 242,591. The OY is reduced by 32,500 mt for the tribal allocation, and 2,000 mt for the estimated catch in non-groundfish fisheries, resulting in a commercial OY of 208,091 mt. The commercial OY is allocated between the sectors, with 42 percent (87,398 mt) going to the shore-based sector, 34 percent (70,751 mt) going to the catcher/processor sector, and 24 percent (49,942 mt) going to the mothership sector. Discards of whiting during the primary season fisheries are estimated and counted towards the OY inseason.

g/ Sablefish - A coastwide sablefish stock assessment was prepared in 2005. The coastwide sablefish biomass was estimated to be at 35.2 percent of its unfished biomass in 2005. Projections indicate that the biomass is increasing and will be near 42 percent of its unfished biomass by 2008. The coastwide ABC of 6,210 mt was based on the base-case assessment model with a F_{MSY} proxy of $F_{45\%}$. The coastwide OY of 5,934 mt is based on the application of the 40-10 harvest policy and is a two year average OY for 2007 and 2008. To apportion fishery allocations for the area north of 36° N. lat., 96.45 percent of the coastwide OY (5,723 mt) is attributed to the northern area. The tribal allocation for the area north of 36° N. lat. is 572 mt (10 percent of the OY north of 36° N. lat), which is further reduced by 1.9 percent (10.9 mt) for discards. The tribal landed catch value is 561.4 mt.

h/ Cabezon was assessed south of 42° N. lat. in 2005. In 2005, the stock was estimated to be at 40 percent of its unfished biomass north of 34° 27' N. lat. and 28 percent of its unfished biomass south of 34° 27' N. lat. The biomass is projected to be increasing in the northern area and decreasing in the southern area. The ABC of 94 mt (71 mt for the northern portion of the stock and 23 mt for the southern portion of the stock) is based on the new assessment with a harvest rate proxy of F_{50}. The OY of 69 mt is a constant harvest level that is consistent with the application of a 60-20 harvest rate policy specified in the California Nearshore Management Plan.

i/ Dover sole was assessed north of 34° 27' N. lat. in 2005. The Dover sole biomass was estimated to be at 59.8 percent of its unfished biomass in 2005 and is projected to be increasing. The ABC of 28,522 mt is based on the results of the 2005 assessment with an F_{MSY} proxy of F_{40}. Because the stock is above B_{40} coastwide, the OY could be set equal to the ABC. The OY of 16,500 mt, which is less than the ABC, is the MSY harvest level and is considerably larger than the coastwide catches in any recent years.

j/ A coastwide English sole stock assessment was prepared in 2005 and the stock was estimated to be at 91.5 percent of its unfished biomass in 2005, but the stock biomass is believed to be declining. The ABC of 6,237 is a 2007-2008 two year average ABC based on the the results of the 2005 assessment with an F_{MSY} proxy of $F_{40\%}$. Because the stock is above $B_{40\%}$, the OY was set equal to the ABC.

k/ A petrale sole stock assessment was prepared for 2005. In 2005 the petrale sole stock coastwide was estimated to be at 32 percent of its unfished biomass (34 percent in the northern assessment area and 29 percent in the southern assessment area). The petrale sole biomass is believed to be increasing. The ABC of 2,917 mt is based on the new assessment with a $F_{40\%}$ F_{MSY} proxy. To derive the OY, the 40-10 harvest policy was applied to the ABC for both the northern and southern assessment areas. As a precautionary measure, an additional 25 percent reduction was made in the OY contribution for the southern area due to assessment uncertainty. The OY of 2,499 mt is the average coastwide OY value for 2007 and 2008.

l/ Arrowtooth flounder was last assessed in 1993 and was estimated to be above 40 percent of its unfished biomass, therefore the OY will be set equal to the ABC.

m/ Starry Flounder was assessed for the first time in 2005 and was estimated to be above 40 percent of its unfished biomass in 2005 (44 percent for the northern stock off Washington and Oregon, and 62 percent for the southern stock of California). The starry flounder biomass is believed to be declining, and will be below $B_{40\%}$. The starry flounder assessment was considered to be a data-poor assessment relative to other groundfish assessments. For 2007, the coastwide ABC of 1,221 mt is based on the new assessment with a F_{MSY} proxy of $F_{40\%}$ and is an average ABC for 2007 and 2008. Because the stock is believed to be above $B_{40\%}$, the OY could be set equal to the ABC. To derive the OY, the 40-10 harvest policy was applied to the ABC for both the northern and southern assessment areas then an additional 25 percent reduction was made due to assessment uncertainty. Starry flounder was previously managed as part of the "other flatfish" category. The OY of 890 mt is the average coastwide OY value for 2007 and 2008.

n/ "Other flatfish" are those flatfish species that do not have individual ABC/OYs and include butter sole, curlfin sole, flathead sole, Pacific sand dab, rex sole, rock sole, and sand sole. Starry flounder was assessed in 2005 and is

being removed from other flatfish complex beginning in 2007. The ABC is based on historical catch levels. The ABC of 6,731 mt is based on the highest landings for sanddabs (1995) and rex sole (1982) for the 1981-2003 period and on the average landings from the 1994-1998 period for the remaining other flatfish species. The OY of 4,884 mt is based on the ABC with a 25 percent precautionary adjustment for sanddabs and rex sole and a 50 percent precautionary adjustment for the remaining species.

o/ A POP stock assessment was prepared in 2005 and the stock was estimated to be at 23.4 percent of its unfished biomass in 2005. The ABC of 900 mt for the Vancouver-Columbia area was projected from the 2005 stock assessment and is based on an F_{MSY} proxy of $F_{50\%}$. The OY of 150 mt is based on a rebuilding plan with a target year to rebuild of 2017 and an SPR harvest rate of 86.4 percent. The OY is reduced by 3.6 mt for the amount anticipated to be taken during research activity.

p/ Shortbelly rockfish remains an unexploited stock and is difficult to assess quantitatively. A 1989 stock assessment provided two alternative yield calculations of 13,900 mt and 47,000 mt. NMFS surveys have shown poor recruitment in most years since 1989, indicating low recent productivity and a naturally declining population in spite of low fishing pressure. The ABC and OY are therefore set at the low end of the range projected in the stock assessment, 13,900 mt.

q/ Widow rockfish was assessed in 2005 and was estimated to be at 31.1 percent of its unfished biomass in 2004. The ABC of 5,334 mt is based on an $F_{50\%}$ F_{MSY} proxy. The OY of 368 mt is based on a rebuilding plan with a target year to rebuild of 2015 and an SPR rate of 95 percent. The OY is reduced by 3.0 mt for the amount anticipated to be taken during research activity. Tribal vessels are estimated to catch about 46.1 mt of widow rockfish in 2007, but do not have a specific allocation at this time. For the Pacific whiting fishery, 200 mt is being set aside and will be managed with bycatch limits.

r/ A canary rockfish stock assessment was completed in 2005 and the stock was estimated to be at 9.4 percent of its unfished biomass coastwide in 2005. The coastwide ABC of 172 mt is based on a F_{MSY} proxy of $F_{50\%}$. The OY of 44 mt is based on a rebuilding plan with a target year to rebuild of 2063 and an SPR harvest rate of 88.7 percent. The OY is reduced by 3.0 mt for the amount anticipated to be taken during research activity. Tribal vessels are estimated to catch about 5 mt of canary rockfish under the 2007 commercial HG, but do not have a specific allocation at this time. South of 42° N. lat., the canary rockfish recreational fishery HG is 9.0 mt and north of 42° N. lat., the canary rockfish recreational fishery HG 8.2 mt.

s/ Chilipepper rockfish was last assessed in 1998. The ABC (2,700 mt) for the Monterey-Conception area is based on a three year average projection from 1999-2001 with a $F_{50\%}$ F_{MSY} proxy. Because the unfished biomass is estimated to be above 40 percent the unfished biomass, the default OY could be set equal to the ABC. However, the OY is set at 2,000 mt to discourage fishing on chilipepper, which is taken with bocaccio. Management measures to constrain the harvest of overfished species have reduced the availability of chilipepper rockfish to the fishery during the past several years. Because the harvest assumptions (from the most recent stock assessment) used to forecast future harvest were likely overestimates, carrying the previously used ABCs and OYs forward into 2007 was considered to be conservative and based on the best available data. Open access is allocated 44.3 percent (886 mt) of the commercial HG and limited entry is allocated 55.7 percent (1,114 mt) of the commercial HG.

t/ A bocaccio stock assessment update and a rebuilding analysis were prepared in 2005. The bocaccio stock was estimated to be at 10.7 percent of its unfished biomass in 2005. The ABC of 602 mt for the Monterey and Conception areas is based on a $F_{50\%}$ F_{MSY} proxy. The OY of 218 mt is based on a rebuilding plan with a target year to rebuild of 2026 and a SPR harvest rate of 77.7 percent. The OY is reduced by 3.0 mt for the amount anticipated to be taken during research activity.

u/ Splitnose rockfish - The ABC is 615 mt in the southern area (Monterey-Conception). The 461 mt OY for the southern area reflects a 25 percent precautionary adjustment because of the less rigorous stock assessment for this stock. Because the harvest assumptions used to forecast future harvest were likely overestimates, carrying the previously used ABCs and OYs forward into 2007 was considered to be conservative and based on the best available data.

v/ Yellowtail rockfish - A yellowtail rockfish stock assessment was prepared in 2005 for the Vancouver-Columbia-Eureka areas. Yellowtail rockfish was estimated to be above 40 percent of its unfished biomass in 2005. The ABC of 4,548 mt is a 2 year average ABC for 2007 and 2008 and is based on the 2005 stock assessment with the F_{MSY} proxy of $F_{50\%}$. The OY of 4,548 mt was set equal to the ABC, because the stock is above the precautionary threshold of $B_{40\%}$. Tribal vessels are estimated to catch about 539 mt of yellowtail rockfish in 2007, but do not have a specific allocation at this time.

w/ Shortspine thornyhead was assessed coastwide in 2005 and the stock was estimated to be at 63 percent of its unfished biomass in 2005. The ABC of 2,476 mt is based on a $F_{50\%}$ F_{MSY} proxy and is the two year average ABC for 2007 and 2008. For that portion of the stock (66 percent of the biomass) north of Pt. Conception (34° 27' N. lat.), the OY of 1,634 mt was set at equal to the ABC because the stock is estimated to be above the precautionary threshold. For that portion of the stock south of Pt. Conception (34 percent of the biomass), the OY of 421 mt was the portion of the ABC for the area reduced by 50 percent as a precautionary adjustment due to the short duration and amount of survey data for that area. Tribal vessels are estimated to catch about 13 mt of shortspine thornyhead in 2007, but do not have a specific allocation at this time.

x/ Longspine thornyhead was assessed coastwide in 2005 and the stock was estimated to be at 71 percent of its unfished biomass in 2005. The coastwide ABC of 3,907 mt is based on a $F_{50\%}$ F_{MSY} proxy and is the two year average OY for the 2007 and 2008 period. The OY is set equal to the ABC because the stock is above the precautionary threshold. Separate OYs are being established for the areas north and south of 34° 27' N. lat. (Point Conception). The OY for that portion of the stock in the northern area (79 percent)is set equal to the ABC. For that portion of the stock in the southern area (21 percent), the OY of 476 mt was the portion of the ABC for the area reduced by 25 percent as a precautionary adjustment due to the short duration and amount of survey data for that area.

y/ Cowcod in the Conception area was assessed in 2005 and was estimated to be between 14 and 21 percent of its unfished biomass. The ABC of in the area south of 36° N. lat., the Conception area, is 17 mt and is based on the 2005 stock assessment with a $F_{50\%}$ F_{MSY} proxy. The ABC for the Monterey area (19 mt) is based on average landings from 1993-1997. A OY of 4 mt is being set for the combined areas. The OY is based on a rebuilding plan with a target year to rebuilding of 2039 and an SPR harvest rate 90 percent. The OY is reduced by 0.1 mt for the amount anticipated to be taken during research activity.

z/ Darkblotched rockfish was assessed in 2005 and was estimated to be at 16 percent of its unfished biomass in 2005. The ABC is projected to be 456 mt and is based on the 2005 stock assessment with an F_{MSY} proxy of F50%. The OY of 290 mt is based on a rebuilding plan with a target year to rebuild of 2011 and an SPR harvest rate of 64.1 percent in 2007. The OY is reduced by 3.8 mt for the amount anticipated to be taken during research activity.

aa/ Yelloweye rockfish was assessed in 2006 and is estimated to be at 17.7 percent of its unfished biomass coastwide. The 26 mt coastwide ABC is based on the new stock assessment and an F_{MSY} proxy of $F_{50\%}$. The 23 mt OY is based on a rebuilding plan with a target year to rebuild of 2084 an SPR harvest rate of 55.4 percent in 2007. The OY is reduced by 3.0 mt for the amount anticipated to be taken during research activity. Tribal vessels are estimated to catch 2.3 mt of yelloweye rockfish of the commercial HG in 2007, but do not have a specific allocation at this time. South of 42° N. lat. the yelloweye rockfish recreational fishery HG is 2.1 mt and north of 42° N. lat. the yelloweye rockfish recreational fishery HG 6.8 mt.

bb/ California Scorpionfish south of 34° 27' N. lat. was assessed in 2005 and was estimated to be above 40 percent of its unfished biomass in 2005. The ABC of 219 mt is based on the new assessment with a harvest rate proxy of $F_{50\%}$ and is an average ABC for 2007 and 2008. Because the stock is above $B_{40\%}$ coastwide, the OY could be set equal to the ABC. The OY of 175 mt, which is lower than the ABC, reflects the highest historical catch levels.

cc/ Black rockfish was last assessed in 2003 for the Columbia and Eureka area and in 2000 for the Vancouver area. The ABC for the area north of 46°16' N. lat. is 540 mt and the ABC for the area south of 46°16' N. lat. is 722 mt which is the average ABC for the 2007 and 2008 period. Because of an overlap in the assessed areas between Cape Falcon and the Columbia River, projections from the 2000 stock assessment were adjusted downward by 12 percent to account for the overlap. The ABCs were derived using an F_{MSY} proxy of $F_{50\%}$. Because the unfished biomass is estimated to be above 40 percent, the OYs were set equal to the ABCs. For the area north of 46°16' N. lat., the OY is

540 mt. The following tribal harvest guidelines are being set: 20,000 lb (9.1 mt) north of Cape Alava, WA (48°09.50' N. lat.) and 10,000 lb (4.5 mt) between Destruction Island, WA (47°40' N. lat.) and Leadbetter Point, WA (46°38.17' N. lat.). For the area south of 46°16' N. lat., the OY is 722 mt. The black rockfish OY in the area south of 46°16' N. lat., is subdivided with separate HGs being set for the area north of 42° N. lat (419 mt/58 percent) and for the area south of 42° N. lat (303 mt/42 percent). For the southern area north of 42° N. lat., a range is presented for the recreational estimate (289-350 mt) and comercial HG (91 -111 mt). Specific values will be specified in the final rule. Of the 303 mt of black rockfish attributed to the area south of 42° N. lat., 168 mt is estimated to be taken in the recreational fisheries, resulting in a commercial HG of 135 mt.

dd/ Minor rockfish north includes the "remaining rockfish" and "other rockfish" categories in the Vancouver, Columbia, and Eureka areas combined. These species include "remaining rockfish", which generally includes species that have been assessed by less rigorous methods than stock assessments, and "other rockfish", which includes species that do not have quantifiable stock assessments. The ABC of 3,680 mt is the sum of the individual "remaining rockfish" ABCs plus the "other rockfish" ABCs. The remaining rockfish ABCs continues to be reduced by 25 percent (F=0.75M) as a precautionary adjustment. To obtain the total catch OY of 2,270 mt, the remaining rockfish ABC was reduced by 25 percent and other rockfish ABC was reduced by 50 percent. This was a precautionary measure to address limited stock assessment information. Tribal vessels are estimated to catch about 38 mt of minor rockfish in 2007, but do not have a specific allocation at this time.

ee/ Minor rockfish south includes the "remaining rockfish" and "other rockfish" categories in the Monterey and Conception areas combined. These species include "remaining rockfish" which generally includes species that have been assessed by less rigorous methods than stock assessment, and "other rockfish" which includes species that do not have quantifiable stock assessments. The ABC of 3,403 mt is the sum of the individual "remaining rockfish" ABCs plus the "other rockfish" ABCs. California scorpionfish is being removed from this category in 2007. Gopher rockfish is being moved from the "other rockfish" group to the remaining rockfish group in 2007. The remaining rockfish ABCs continue to be reduced by 25 percent (F=0.75M) as a precautionary adjustment. The remaining rockfish ABCs are further reduced by 25 percent, with the exception of blackgill rockfish (see footnote gg). The other rockfish ABCs were reduced by 50 percent. This was a precautionary measure due to limited stock assessment information. The resulting minor rockfish OY is 1,904 mt.

ff/ Bank rockfish - The ABC is 350 mt which is based on a 2000 stock assessment for the Monterey and Conception areas. This stock contributes 263 mt towards the minor rockfish OY in the south.

gg/ Blackgill rockfish in the Monterey and Conception areas was assessed in 2005 and is estimated to be at 50.6 percent of its unfished biomass in 2005. The ABC of 292 mt for Monterey and Conception areas is based on the 2005 stock assessment with an F_{MSY} proxy of F50% and is the two year average ABC for the 2007 and 2008 periods. This stock contributes 292 mt towards minor rockfish south.

hh/ "Other rockfish" includes rockfish species listed in 50 CFR 660.302. California scorpionfish and gopher rockfish were assessed in 2005 and are being removed from this category. The California Scorpionfish contribution of 163 mt and the gopher rockfish contribution of 97 mt were removed from the ABC value. The ABC for the remaining species is based on the 1996 review of commercial Sebastes landings and includes an estimate of recreational landings. These species have never been assessed quantitatively.

ii/ "Other fish" includes sharks, skates, rays, ratfish, morids, grenadiers, kelp greenling and other groundfish species noted above in footnote d/.

■ 5. Tables 3 (North) and 3 (South) to part 660 subpart G are revised to read as follows.

BILLING CODE 3510–22–P

Table 3 (North) to Part 660, Subpart G -- 2007-2008 Trip Limits for Limited Entry Trawl Gear North of 40°10' N. Lat.

Other Limits and Requirements Apply -- Read § 660.301 - § 660.399 before using this table 032007

	JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
Rockfish Conservation Area (RCA)[6/]:						
North of 48°10.00' N. lat.	75 fm - modified 250 fm [7/]	75 fm - 250 fm	shore - 150 fm		shore - 200 fm	shore - modified 200 fm [7/]
48°10.00' N. lat. - 46°38.17' N. lat.			75 fm - 150 fm		75 fm - 200 fm	75 fm - modified 200 fm [7/]
46°38.17' N. lat. - 46°16.00 N. lat.			60 fm -150 fm		60 fm -200 fm	75 fm - modified 200 fm [7/]
46°16.00 N. lat. - 45°03.83 N. lat.			75 fm - 150 fm		75 fm - 200 fm	75 fm - modified 200 fm [7/]
45°03.83' N. lat. - 43°20.83' N. lat.			75 fm - 200 fm			75 fm - modified 200 fm [7/]
43°20.83' N. lat. - 42°40.50' N. lat.			shore - 200fm			shore - modified 200 fm [7/]
42°40.50' N. lat. -40°10.00' N. lat.			75 fm - 200 fm			75 fm - modified 200 fm [7/]

Selective flatfish trawl gear is required shoreward of the RCA; all trawl gear (large footrope, selective flatfish trawl, and small footrope trawl gear) is permitted seaward of the RCA. Large footrope trawl gear is prohibited shoreward of the RCA. Midwater trawl gear is permitted only for vessels participating in the primary whiting season.

See § 660.370 and § 660.381 for Additional Gear, Trip Limit, and Conservation Area Requirements and Restrictions. See §§ 660.390-660.394 and §§ 660.396-660.399 for Conservation Area Descriptions and Coordinates (including RCAs, YRCA, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).

State trip limits and seasons may be more restrictive than federal trip limits, particularly in waters off Oregon and California.

1	**Minor slope rockfish[2/] & Darkblotched rockfish**	4,000 lb/ 2 months		1,500 lb/ 2 months		
2	**Pacific ocean perch**	3,000 lb/ 2 months				
3	**DTS complex**					
4	Sablefish					
5	large & small footrope gear	13,000 lb/ 2 months		15,000 lb/ 2 months		13,000 lb/ 2 months
6	selective flatfish trawl gear	5,000 lb/ 2 months	8,000 lb/ 2 months	5,000 lb/ 2 months		
7	multiple bottom trawl gear [8/]	5,000 lb/ 2 months	8,000 lb/ 2 months	5,000 lb/ 2 months		
8	Longspine thornyhead					
9	large & small footrope gear	22,000 lb/ 2 months				
10	selective flatfish trawl gear	3,000 lb/ 2 months				
11	multiple bottom trawl gear [8/]	3,000 lb/ 2 months				
12	Shortspine thornyhead					
13	large & small footrope gear	7,500 lb/ 2 months		10,000 lb/ 2 months		
14	selective flatfish trawl gear	3,000 lb/ 2 months				
15	multiple bottom trawl gear [8/]	3,000 lb/ 2 months				
16	Dover sole					
17	large & small footrope gear	80,000 lb/ 2 months		60,000 lb/ 2 months		80,000 lb/ 2 months
18	selective flatfish trawl gear	40,000 lb/ 2 months		38,000 lb/ 2 months		25,000 lb/ 2 months
19	multiple bottom trawl gear [8/]	40,000 lb/ 2 months		38,000 lb/ 2 months		25,000 lb/ 2 months

TABLE 3 (North)

Table 3 (North). Continued

20	**Whiting**					
21	midwater trawl	Before the primary whiting season: CLOSED. -- During the primary season: mid-water trawl permitted in the RCA. See §660.373 for season and trip limit details. -- After the primary whiting season: CLOSED.				
22	large & small footrope gear	Before the primary whiting season: 20,000 lb/trip. -- During the primary season: 10,000 lb/trip. -- After the primary whiting season: 10,000 lb/trip.				
23	**Flatfish** (except Dover sole)					
24	Arrowtooth flounder					
25	large & small footrope gear	100,000 lb/ 2 months		Arrowtooth included within other flatfish limits - - see below		
26	selective flatfish trawl gear	90,000 lb/ 2 months				
27	multiple bottom trawl gear [8/]	90,000 lb/ 2 months				
28	Other flatfish [3/], English sole, starry flounder, & Petrale sole					
29	large & small footrope gear for Other flatfish[3/], English sole, & starry flounder	110,000 lb/ 2 months	110,000 lb/ 2 months, no more than 30,000 lb/ 2 months of which may be petrale sole.	110,000 lb/ 2 months (including arrowtooth), no more than 20,000 lb/ 2 months of which may be petrale sole.		110,000 lb/ 2 months (including arrowtooth)
30	large & small footrope gear for Petrale sole	50,000 lb/ 2 months				30,000 lb/ 2 months
31	selective flatfish trawl gear for Other flatfish[3/], English sole, & starry flounder	90,000 lb/ 2 months, no more than 16,000 lb/ 2 months of which may be petrale sole.	90,000 lb/ 2 months, no more than 25,000 lb/ 2 months of which may be petrale sole.	70,000 lb/ 2 months (including arrowtooth), no more than 20,000 lb/ 2 months of which may be petrale sole.	70,000 lb/ 2 months (including arrowtooth), no more than 15,000 lb/ 2 months of which may be petrale sole.	30,000 lb/ 2 months (including arrowtooth), no more than 8,000 lb/ 2 months of which may be petrale sole.
32	selective flatfish trawl gear for Petrale sole					
33	multiple bottom trawl gear [8/]	90,000 lb/ 2 months, no more than 16,000 lb/ 2 months of which may be petrale sole.	90,000 lb/ 2 months, no more than 25,000 lb/ 2 months of which may be petrale sole.	70,000 lb/ 2 months (including arrowtooth), no more than 20,000 lb/ 2 months of which may be petrale sole.	70,000 lb/ 2 months (including arrowtooth), no more than 15,000 lb/ 2 months of which may be petrale sole.	30,000 lb/ 2 months (including arrowtooth), no more than 8,000 lb/ 2 months of which may be petrale sole.
34	**Minor shelf rockfish[1/], Shortbelly, Widow & Yelloweye rockfish**					
35	midwater trawl for Widow rockfish	Before the primary whiting season: CLOSED. -- During primary whiting season: In trips of at least 10,000 lb of whiting, combined widow and yellowtail limit of 500 lb/ trip, cumulative widow limit of 1,500 lb/ month. Mid-water trawl permitted in the RCA. See §660.373 for primary whiting season and trip limit details. -- After the primary whiting season: CLOSED.				
36	large & small footrope gear	300 lb/ 2 months				
37	selective flatfish trawl gear	300 lb/ month		1,000 lb/ month, no more than 200 lb/ month of which may be yelloweye rockfish		300 lb/ month
38	multiple bottom trawl gear [8/]	300 lb/ month		300 lb/ 2 months, no more than 200 lb/ month of which may be yelloweye rockfish		300 lb/ month

TABLE 3 (North) con't

Table 3 (North). Continued

39	**Canary rockfish**				
40	large & small footrope gear	CLOSED			
41	selective flatfish trawl gear	100 lb/ month	300 lb/ month	100 lb/ month	
42	multiple bottom trawl gear [8/]	CLOSED			
43	**Yellowtail**				
44	midwater trawl	Before the primary whiting season: CLOSED. -- During primary whiting season: In trips of at least 10,000 lb of whiting: combined widow and yellowtail limit of 500 lb/ trip, cumulative yellowtail limit of 2,000 lb/ month. Mid-water trawl permitted in the RCA. See §660.373 for primary whiting season and trip limit details. -- After the primary whiting season: CLOSED.			
45	large & small footrope gear	300 lb/ 2 months			
46	selective flatfish trawl gear	2,000 lb/ 2 months			
47	multiple bottom trawl gear [8/]	300 lb/ 2 months			
48	**Minor nearshore rockfish & Black rockfish**				
49	large & small footrope gear	CLOSED			
50	selective flatfish trawl gear	300 lb/ month			
51	multiple bottom trawl gear [8/]	CLOSED			
52	**Lingcod** [4/]				
53	large & small footrope gear	1,200 lb/ 2 months	4,000 lb/ 2 months		
54	selective flatfish trawl gear				
55	multiple bottom trawl gear [8/]		1,200 lb/2 months		
56	**Pacific cod**	30,000 lb/ 2 months	70,000 lb/ 2 months		30,000 lb/ 2 months
57	**Spiny dogfish**	200,000 lb/ 2 months	150,000 lb/ 2 months	100,000 lb/ 2 months	
58	**Other Fish** [5/]	Not limited			

TABLE 3 (North) con't

1/ Bocaccio, chilipepper and cowcod are included in the trip limits for minor shelf rockfish.
2/ Splitnose rockfish is included in the trip limits for minor slope rockfish.
3/ "Other flatfish" are defined at § 660.302 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.
4/ The minimum size limit for lingcod is 24 inches (61 cm) total length.
5/ "Other fish" are defined at § 660.302 and include sharks, skates, ratfish, morids, grenadiers, and kelp greenling. Cabezon is included in the trip limits for "other fish."
6/ The Rockfish Conservation Area is a gear and/or sector specific closed area generally described by depth contours but specifically defined by lat/long coordinates set out at §§ 660.391-660.394.
7/ The "modified 200 fm" line is modified to exclude certain petrale sole areas from the RCA.
8/ If a vessel has both selective flatfish gear and large or small footrope gear on board during a cumulative limit period (either simultaneously or successively), the most restrictive cumulative limit for any gear on board during the cumulative limit period applies for the entire cumulative limit period.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Table 3 (South) to Part 660, Subpart G -- 2007-2008 Trip Limits for Limited Entry Trawl Gear South of 40°10' N. Lat.

Other Limits and Requirements Apply -- Read § 660.301 - § 660.399 before using this table 032007

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[6/]:						
	40°10' - 38° N. lat.	100 fm - modified 200 fm [7/]	100 fm - 150 fm				100 fm - modified 200 fm [7/]
	38° - 34°27' N. lat.	100 fm - 150 fm					
	South of 34°27' N. lat.	100 fm - 150 fm along the mainland coast; shoreline - 150 fm around islands					
	All trawl gear (large footrope, selective flatfish trawl, and small footrope trawl gear) is permitted seaward of the RCA. Large footrope trawl gear is prohibited shoreward of the RCA. Midwater trawl gear is permitted only for vessels participating in the primary whiting season.						
	See § 660.370 and § 660.381 for Additional Gear, Trip Limit, and Conservation Area Requirements and Restrictions. See §§ 660.390-660.394 and §§ 660.396-660.399 for Conservation Area Descriptions and Coordinates (including RCAs, YRCA, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).						
	State trip limits and seasons may be more restrictive than federal trip limits, particularly in waters off Oregon and California.						
1	**Minor slope rockfish[2/] & Darkblotched rockfish**						
2	40°10' - 38° N. lat.	15,000 lb/ 2 months			10,000 lb/ 2 months		15,000 lb/ 2 months
3	South of 38° N. lat.	40,000 lb/ 2 months					
4	**Splitnose**						
5	40°10' - 38° N. lat.	15,000 lb/ 2 months			10,000 lb/ 2 months		15,000 lb/ 2 months
6	South of 38° N. lat.	40,000 lb/ 2 months					
7	**DTS complex**						
8	Sablefish	14,000 lb/ 2 months					
9	Longspine thornyhead	22,000 lb/ 2 months					
10	Shortspine thornyhead	7,500 lb/ 2 months					
11	Dover sole	70,000 lb/ 2 months					
12	**Flatfish** (except Dover sole)						
13	Other flatfish[3/], English sole, & starry flounder						
14	40°10' - 38° N. lat.	110,000 lb/ 2 months	Other flatfish, English sole, starry flounder & Petrale sole: 110,000 lb/ 2 months, no more than 30,000 lb/ 2 months of which may be petrale sole.	Other flatfish, English sole, starry flounder, arrowtooth flounder & Petrale sole: 110,000 lb/ 2 months, no more than 25,000 lb/ 2 months of which may be petrale sole.			110,000 lb/ 2 months (including arrowtooth)
15	South of 38° N. lat.						
16	Petrale sole	50,000 lb/ 2 months					50,000 lb/ 2 months
17	Arrowtooth flounder						
18	40°10' - 38° N. lat.	10,000 lb/ 2 months		Arrowtooth included within other flatfish limits - - see above			
19	South of 38° N. lat.						
20	**Whiting**						
21	midwater trawl	Before the primary whiting season: CLOSED. -- During the primary season: mid-water trawl permitted in the RCA. See §660.373 for season and trip limit details. -- After the primary whiting season: CLOSED.					
22	large & small footrope gear	Before the primary whiting season: 20,000 lb/trip. -- During the primary season: 10,000 lb/trip. -- After the primary whiting season: 10,000 lb/trip.					

TABLE 3 (South)

Table 3 (South). Continued

23	**Minor shelf rockfish[1/], Chilipepper, Shortbelly, Widow, & Yelloweye rockfish**			
24	large footrope or midwater trawl for Minor shelf rockfish & Shortbelly	300 lb/ month		
25	large footrope or midwater trawl for Chilipepper	2,000 lb/ 2 months	12,000 lb/ 2 months	8,000 lb/ 2 months
26	large footrope or midwater trawl for Widow & Yelloweye	CLOSED		
27	small footrope trawl for Minor Shelf, Shortbelly, Widow & Yelloweye	300 lb/ month		
28	small footrope trawl for Chilipepper	500 lb/ month		
29	**Bocaccio**			
30	large footrope or midwater trawl	300 lb/ 2 months		
31	small footrope trawl	CLOSED		
32	**Canary rockfish**			
33	large footrope or midwater trawl	CLOSED		
34	small footrope trawl	100 lb/ month	300 lb/ month	100 lb/ month
35	**Cowcod**	CLOSED		
36	**Minor nearshore rockfish & Black rockfish**			
37	large footrope or midwater trawl	CLOSED		
38	small footrope trawl	300 lb/ month		
39	**Lingcod[4/]**			
40	large footrope or midwater trawl	1,200 lb/ 2 months	4,000 lb/ 2 months	
41	small footrope trawl		1,200 lb/ 2 months	
42	**Pacific cod**	30,000 lb/ 2 months	70,000 lb/ 2 months	30,000 lb/ 2 months
43	**Spiny dogfish**	200,000 lb/ 2 months	150,000 lb/ 2 months	100,000 lb/ 2 months
44	**Other Fish[5/] & Cabezon**	Not limited		

TABLE 3 (South) con't

1/ Yellowtail is included in the trip limits for minor shelf rockfish.
2/ POP is included in the trip limits for minor slope rockfish
3/ "Other flatfish" are defined at § 660.302 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.
4/ The minimum size limit for lingcod is 24 inches (61 cm) total length.
5/ Other fish are defined at § 660.302 and include sharks, skates, ratfish, morids, grenadiers, and kelp greenling.
6/ The Rockfish Conservation Area is a gear and/or sector specific closed area generally described by depth contours but specifically defined by lat/long coordinates set out at §§ 660.391-660.394.
7/ The "modified 200 fm" line is modified to exclude certain petrale sole areas from the RCA.
To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

[FR Doc. 07–1917 Filed 4–17–07; 8:45 am]
BILLING CODE 3510–22–C

Proposed Rules

Federal Register
Vol. 72, No. 74
Wednesday, April 18, 2007

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 213

[DOD–2006–OS–0107]

RIN 0790–AI18

Support for Non-Federal Entities Authorized To Operate on DoD Installations

AGENCY: Department of Defense.

ACTION: Proposed rule.

SUMMARY: This rule establishes policy and assigns responsibilities under DoD Directive 5124.8 for standardizing support to Non-Federal entities authorized to operate on DoD installations. Designates the Secretary of Army as the DoD executive agent for: Support to Boy Scout and Girl Scout local councils and organizations in areas outside of the United States; support for the national Boy Scout jamboree; the annual DoD audit of the American Red Cross (ARC) accounts and the subsequent report to Congress; and necessary ARC deployment support. It also designates the Secretary of the Air Force as the DoD Executive Agent for conducting the Armed Forces Entertainment program. It will have minimal impact on the public.

DATES: Comments must be received by June 18, 2007. Do not submit comments directly to the point of contact or mail your comments to any address other than what is shown below. Doing so will delay the posting of the submission.

ADDRESSES: You may submit comments, identified by docket number and or RIN number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Pam Crespi 703–602–5004.

SUPPLEMENTARY INFORMATION:

Executive Order 12866, ''Regulatory Planning and Review''

This proposed regulatory action is not a significant regulatory action, as defined by Executive Order 12866 and does not:

(1) Have an annual effect to the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4)

The proposed regulatory action does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The proposed regulatory action is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The rule establishes policy and assigns executive agent responsibilities but taken cumulatively, those changes would not have a significant impact on a substantial number of small entities.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

The proposed regulatory action does impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, ''Federalism''

The proposed regulatory action does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 213

Federal buildings and facilities.

Accordingly, 32 CFR part 213 is proposed to be added to read as follows:

PART 213—SUPPORT FOR NON-FEDERAL ENTITIES AUTHORIZED TO OPERATE ON DOD INSTALLATIONS

Sec.
213.1 Purpose.
213.2 Applicability and scope.
213.3 Definition.
213.4 Policy.
213.5 Responsibilities

Authority: 10 U.S.C. 2554 and 2606.

§ 213.1 Purpose.

This part:

(a) Authorizes 32 CFR part 212.

(b) Establishes policy and assigns responsibilities under DoD Directive 5124.8 [1] for standardizing support to non-Federal entities authorized to operate on DoD installations.

(c) Designates the Secretary of the Army as the DoD Executive Agent (DoD EA) according to DoD Directive 5101.1: [2]

(1) For DoD support to the Boy Scouts of America (BSA) and Girl Scouts of the United States of America (GSUSA) local councils and organizations in areas outside of the United States 10 U.S.C. 2606. DoD support will also cover the periodic national jamboree according to 10 U.S.C. 2606.[3]

[1] Copies may be obtained at *http://www.dtic.mil/whs/directives/.*

[2] Copies may be obtained at *http://www.dtic.mil/whs/directives/.*

[3] A Federal district judge has ruled that support to BSA under section 2554 of Reference (g) is

Continued

(2) To perform the annual audit of the American Red Cross (ARC) accounts and to prepare and submit the annual report to Congress according to 36 U.S.C. 300110.

(3) To provide the ARC with the necessary deployment support.

(d) Designates the Secretary of the Air Force as the DoD EA responsible for conducting the Armed Forces Entertainment (AFE) program.

§ 213.2 Applicability and scope.

This part:

(a) Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the ''DoD Components'') and non-Federal entities authorized to operate on DoD installations.

(b) Shall not revise, modify, or rescind any Memorandum of Understanding (MOU) between a non-Federal entity and the U.S. Government or the Department of Defense or their implementing arrangements in existence as of the effective date of this Directive. Additionally, the Directive shall not revise, modify, or rescind any MOU between the Department of Justice (DoJ) and the Department of Defense that is in existence as of the effective date of this Directive. Any such agreements shall, as they expire, come up for renewal, or as circumstances otherwise permit, be revised to conform to this Directive and any implementing guidance.

(c). Does not apply to banks or credit unions addressed in DoD Directive 1000.11 [4] or the Civil Air Patrol according to 10 U.S.C. 2554.

§ 213.3 Definition.

Non-federal entities. A non-Federal entity is generally a self-sustaining, non-Federal person or organization, established, operated, and controlled by any individual(s) acting outside the scope of any official capacity as officers, employees, or agents of the Federal Government. This Directive addresses only those entities that may operate on DoD installations with the express consent of the installation commander or higher authority under applicable regulations. Non-Federal entities may include elements of state, interstate, Indian tribal, and local government, as well as private organizations.

§ 213.4 Policy.

It is DoD policy that:

(a) DoD support for non-Federal entities shall be in accordance with relevant statutes as well as DoD 5500.7–R.[5] In accordance with DoD 5500.7–R and to avoid preferential treatment, DoD support should be uniform, recognizing that non-Federal entity support of Service members and their families can be important to their welfare.

(b) Under DoD Directive 5124.8 procedures shall be established as Instructions and agreements for the operation of non-Federal entities on DoD installations and for the prohibition of official sanction, endorsement, or support by the DoD Components and officials, except as authorized by DoD 5500.7–R and applicable law. Instructions and agreements must be compatible with the primary mission of the Department and provide for Congressionally authorized support to non-Federal entities on DoD installations.

(c) In accordance with DoD 5500.7–R, installation commanders or higher authority may authorize, in writing, logistical support for events, including fundraising events, sponsored by non-Federal entities covered by this part.

(d) Installation commanders or higher authority may coordinate with non-Federal entities in order to support appropriated or nonappropriated fund activities on DoD installations, so long as the support provided by the non-Federal entities does not compete with appropriated or nonappropriated fund activities.

(e) Non-Federal entities are not entitled to sovereign immunity and the privileges given to Federal entities and instrumentalities.

§ 213.5 Responsibilities.

(a) The Principal Deputy Under Secretary of Defense for Personnel and Readiness (PDUSD(P&R)), under the Under Secretary of Defense for Personnel and Readiness, shall:

(1) Be responsible for implementing all policy matters and Office of the Secretary of Defense oversight of non-Federal entities on DoD installations.

(2) Develop procedures and execute any necessary agreements to implement policy for the operation of non-Federal entities on DoD installations.

(3) Assign responsibilities to the DoD Components to accomplish specific oversight and administrative responsibilities with respect to non-Federal entities operating on DoD installations.

(4) Oversee the activities of the designated DoD EA, assessing the need for continuation, currency, effectiveness, and efficiency of the DoD EA according to 10 U.S.C. 2554. Make recommendations for establishment of additional DoD EA assignments and arrangements as necessary.

(b) The Secretary of the Army, as the designated DoD EA, and according to 10 U.S.C. 2554, shall:

(1) Perform the audit of the annual ARC accounts and prepare and submit the annual report according to 36 U.S.C. 300110 and this part.

(2) Coordinate support to the BSA and GSUSA according to DoD Instruction 1015.9 [6] and this part.

(3) Provide necessary deployment support to ARC according to an approved DoD and ARC MOU. Initially, the Army will cover costs, except those paid by the ARC. The Army will then be reimbursed, upon its request, by the entity directly benefiting from the ARC support.

(4) Designate a point of contact to coordinate matters regarding the DoD EA responsibilities, functions, and authorities.

(c) The Secretary of the Air Force, as the designated DoD EA with responsibility for conducting the AFE program, shall administer the AFE program according to 10 U.S.C. 2554, DoD Instruction 1330.13,[7] and this part to include the following:

(1) Annually determine with the other DoD Components and the PDUSD (P&R) the scope of the program.

(2) Budget, fund, and maintain accountability for approved appropriated fund expenses. Develop and implement supplemental guidance to identify allowable expenses and reimbursements.

(3) Provide centralized services for selecting, declining, scheduling, and processing entertainment groups for overseas.

(4) Designate a point of contact to coordinate matters regarding the DoD EA responsibilities, functions, and authorities.

unconstitutional, and has enjoined the Department of Defense from providing future support under that statute. The Department of Defense is appealing that order. However, unless the order is overturned on appeal, the Department of Defense cannot provide any support to BSA using this statute. Contact your local legal office for further guidance.

[4] Copies may be obtained at *http://www.dtic.mil/whs/directives/*.

[5] Copies may be obtained at *http://www.dtic.mil/whs/directives/*.

[6] Copies may be obtained at *http://www.dtic.mil/whs/directives/*.

[7] Copies may be obtained at *http://www.dtic.mil/whs/directives/*.

Dated: April 11, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. E7–7247 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2006–0305; FRL–8301–8]

Determination of Attainment, Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Indiana; Redesignation of the South Bend-Elkhart 8-Hour Nonattainment Area to Attainment for Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On May 30, 2006, the Indiana Department of Environmental Management (IDEM) submitted a request for EPA approval of a redesignation of St. Joseph and Elkhart Counties to attainment of the 8-hour ozone National Ambient Air Quality Standard (NAAQS) and of an ozone maintenance plan for St. Joseph and Elkhart Counties as a revision to the Indiana State Implementation Plan (SIP). Today, EPA is proposing to approve Indiana's request and corresponding SIP revision. EPA is also proposing to approve the Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Motor Vehicle Emission Budgets (MVEBs) for these Counties, as supported by the ozone maintenance plan for this area, for purposes of transportation conformity determinations.

DATES: Comments must be received on or before May 18, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–0305, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: mooney.john@epa.gov.*
- *Fax:* (312) 886–5824.
- *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
- *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois. Such deliveries are only accepted during the Regional Office's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office's official hours of operation are Monday through Friday, 8:30 AM to 4:30 PM, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2006–0305. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through www.regulations.gov or e-mail. The www.regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and should be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hardcopy. Publicly available docket materials are available either electronically in www.regulations.gov or in hardcopy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. It is recommended that you telephone Steven Rosenthal, Environmental Engineer, at (312) 886–6052, before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Steven Rosenthal, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6052, *doty.edward@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA. This supplementary information section is arranged as follows:

I. What Action Is EPA Proposing to Take?
II. What Is the Background for This Action?
III. What Are the Criteria for Redesignation to Attainment?
IV. What Are EPA's Analyses of the State's Requests and What Are the Bases for EPA's Proposed Action?
V. Has Indiana Adopted Acceptable Motor Vehicle Emissions Budgets for the End of the 14-Year Maintenance Plan Which Can Be Used To Support Transportation Conformity Determinations?
VI. What Is the Effect of EPA's Proposed Action?
VII. Statutory and Executive Order Reviews

I. What Action is EPA Proposing to Take?

We are proposing to take several related actions for St. Joseph and Elkhart Counties. First, we are proposing to determine that St. Joseph and Elkhart Counties have attained the 8-hour ozone NAAQS based on air quality for the period of 2003 through 2005. Second, we are proposing to approve Indiana's ozone maintenance plan for St. Joseph and Elkhart Counties as a revision of the Indiana SIP. The maintenance plan is designed to keep St. Joseph and Elkhart Counties in attainment of the 8-hour ozone standard through 2020. As supported by and consistent with the ozone maintenance plan, we are also proposing to approve the 2020 VOC and NO_X MVEBs for St. Joseph and Elkhart Counties for transportation conformity purposes. Finally, we are proposing to approve the request from the State of Indiana to change the designation of St. Joseph and Elkhart Counties from nonattainment to attainment of the 8-hour ozone NAAQS. We have determined that the State and St. Joseph and Elkhart Counties have met the requirements for redesignation to attainment under section 107(d)(3)(E) of the Clean Air Act (CAA).

II. What Is the Background for This Action?

A. General Background Information

EPA has determined that ground-level ozone is detrimental to human health. On July 18, 1997, EPA promulgated an 8-hour ozone NAAQS of 0.08 parts per million parts of air (0.08 ppm) (80 parts per billion (ppb)) (62 FR 38856).[1] This 8-hour ozone standard replaced a prior 1-hour ozone NAAQS, which had been promulgated on February 8, 1979 (44 FR 8202), and which was revoked on June 15, 2005 (69 FR 23858).

Ground-level ozone is not emitted directly by sources. Rather, emitted NO_X and VOC react in the presence of sunlight to form ground-level ozone along with other secondary compounds. NO_X and VOC are referred to as ''ozone precursors.'' Control of ground-level ozone concentrations is achieved through controlling VOC and NO_X emissions.

The CAA required EPA to designate as nonattainment any area that violated the 8-hour ozone NAAQS. The **Federal Register** notice promulgating these designations and classifications was published on April 30, 2004 (69 FR 23857).

The CAA contains two sets of provisions—subpart 1 and subpart 2—that address planning and emission control requirements for nonattainment areas. Both are found in title I, part D of the CAA. Subpart 1 contains general, less prescriptive requirements for all nonattainment areas for any pollutant governed by a NAAQS. Subpart 2 contains more specific requirements for certain ozone nonattainment areas, and applies to ozone nonattainment areas classified under section 181 of the CAA.

In the April 30, 2004 designation rulemaking, EPA divided 8-hour ozone nonattainment areas into the categories of subpart 1 nonattainment (''basic'' nonattainment) and subpart 2 nonattainment (''classified'' nonattainment). EPA based this division on the area's 8-hour ozone design values (i.e., on the three-year averages of the annual fourth-highest daily maximum 8-hour ozone concentrations at the worst-case monitoring sites in the areas) and on their 1-hour ozone design values (i.e., on the fourth-highest daily maximum 1-hour ozone concentrations over the three-year period at the worst-case monitoring sites in the areas).[2] EPA classified 8-hour ozone nonattainment areas with 1-hour ozone design values equaling or exceeding 121 ppb as subpart 2, classified nonattainment areas. EPA classified all other 8-hour nonattainment areas as subpart 1, basic nonattainment areas. The basis for area classification was defined in a separate April 30, 2004 final rule (the Phase 1 implementation rule) (69 FR 23951).

Emission control requirements for classified nonattainment areas are linked to area classifications. Areas with more serious ozone pollution problems are subject to more prescribed requirements and later attainment dates. The prescribed emission control requirements are designed to bring areas into attainment by their specified attainment dates.

In the April 30, 2004, ozone designation/classification rulemaking, EPA designated St. Joseph and Elkhart Counties as a subpart 1 basic nonattainment area for the 8-hour ozone NAAQS. EPA based designation on ozone data collected during the 2001–2003 period.

On May 30, 2006, the State of Indiana requested redesignation of St. Joseph and Elkhart Counties to attainment of the 8-hour ozone NAAQS based on ozone data collected in these Counties from 2003–2005.

B. What Is the Impact of the December 22, 2006 United States Court of Appeals Decision Regarding EPA's Phase 1 Implementation Rule?

1. Summary of Court Decision

On December 22, 2006, the U.S. Court of Appeals for the District of Columbia Circuit vacated EPA's Phase 1 Implementation Rule for the 8-hour Ozone Standard. (69 FR 23951, April 30, 2004). *South Coast Air Quality Management Dist.* v. *EPA*, 472 F.3d 882 (D.C.Cir. 2006). The Court held that certain provisions of EPA's Phase I Rule were inconsistent with the requirements of the Clean Air Act. The Court rejected EPA's reasons for implementing the 8-hour standard in nonattainment areas under Subpart 1 in lieu of subpart 2 of Title I, part D of the Act. The Court also held that EPA improperly failed to retain four measures required for 1-hour nonattainment areas under the anti-backsliding provisions of the regulations: (1) Nonattainment area New Source Review (NSR) requirements based on an area's 1-hour nonattainment classification; (2) Section 185 penalty fees for 1-hour severe or extreme nonattainment areas; (3) measures to be implemented pursuant to section 172(c)(9) or 182(c)(9)of the Act, on the contingency of an area not making reasonable further progress toward attainment of the 1-hour NAAQS, or for failure to attain that NAAQS; and (4) certain conformity requirements for certain types of Federal actions. The Court upheld EPA's authority to revoke the 1-hour standard provided there were adequate anti-backsliding provisions.

This section sets forth EPA's views on the potential effect of the Court's ruling on this redesignation action. For the reasons set forth below, EPA does not believe that the Court's ruling alters any requirements relevant to this redesignation action so as to preclude redesignation, and does not prevent EPA from finalizing this redesignation. EPA believes that the Court's decision, as it currently stands or as it may be modified based upon any petition for rehearing that has been filed, imposes no impediment to moving forward with redesignation of this area to attainment, because in either circumstance redesignation is appropriate under the relevant redesignation provisions of the Act and longstanding policies regarding redesignation requests.

2. Requirements Under the 8-Hour Standard

With respect to the 8-hour standard, the Court's ruling rejected EPA's reasons for classifying areas under Subpart 1 for the 8-hour standard, and remanded that matter to the Agency. Consequently, it is possible that this area could, during a remand to EPA, be reclassified under Subpart 2. Although any future decision by EPA to classify this area under Subpart 2 might trigger additional future requirements for the area, EPA believes that this does not mean that redesignation cannot now go forward. This belief is based upon (1) EPA's longstanding policy of evaluating requirements in accordance with the requirements due at the time the request is submitted; (2) consideration of the inequity of applying retroactively any requirements that might in the future be applied; and, (3) the fact that the redesignation request preceded even the earliest possible due dates of any requirements for Subpart 2 areas.

First, at the time the redesignation request was submitted, St. Joseph and Elkhart Counties were classified under Subpart 1 and were obligated to meet Subpart 1 requirements. Under EPA's longstanding interpretation of section 107(d)(3)(E) of the Clean Air Act, to

[1] This standard is violated in an area when any ozone monitor in the area (or in its impacted downwind environs) records 8-hour ozone concentrations with an average of the annual fourth-highest daily maximum 8-hour ozone concentrations over a three-year period equaling or exceeding 85 ppb. 40 CFR 50.10.

[2] The 8-hour ozone design value and the 1-hour ozone design value for each area were not necessarily recorded at the same monitoring site. The worst-case monitoring site for each ozone concentration averaging time was considered for each area.

qualify for redesignation, states requesting redesignation to attainment must meet only the relevant SIP requirements that came due prior to the submittal of a complete redesignation request. September 4, 1992, Calcagni memorandum (''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division) See also Michael Shapiro Memorandum, September 17, 1993, and 60 FR 12459, 12465–66 (March 7, 1995)(Redesignation of Detroit-Ann Arbor). See *Sierra Club* v. *EPA*, 375 F.3d 537 (7th Cir. 2004), which upheld this interpretation. See, *e.g.* also 68 FR 25418, 25424, 25427 (May 12, 2003) (redesignation of St. Louis).

Moreover, it would be inequitable to retroactively apply any new SIP requirements that were not applicable at the time the request was submitted. The D.C. Circuit has recognized the inequity in such retroactive rulemaking, See *Sierra Club* v. *Whitman*, 285 F. 3d 63 (D.C. Cir. 2002), in which the D.C. Circuit upheld a District Court's ruling refusing to make retroactive an EPA determination of nonattainment that was past the statutory due date. Such a determination would have resulted in the imposition of additional requirements on the area. The Court stated: ''Although EPA failed to make the nonattainment determination within the statutory time frame, Sierra Club's proposed solution only makes the situation worse. Retroactive relief would likely impose large costs on the States, which would face fines and suits for not implementing air pollution prevention plans in 1997, even though they were not on notice at the time.'' *Id.* at 68. Similarly here it would be unfair to penalize the area by applying to it for purposes of redesignation additional SIP requirements under Subpart 2 that were not in effect at the time it submitted its redesignation request.

For the reasons indicated above, EPA believes it would be inequitable to evaluate a redesignation request based on Subpart 2 requirements that might apply in the future. But even if a future Subpart 2 classification applied retroactively, the applicable requirements for purposes of redesignation are only those that became due prior to submission of the redesignation request. In the case of St. Joseph and Elkhart Counties the redesignation request was submitted on May 30, 2006, and thus preceded even the earliest possible due date of requirements for areas classified under Subpart 2 effective June 2004. The earliest such submission date was June 15, 2006, for the emissions statements requirement under section 182(a)(3)(B) and emissions inventories under section 182(a)(1). Thus for this additional reason alone these additional Subpart 2 requirements would not be applicable for purposes of evaluating a redesignation request for this area.

3. Requirements Under the 1-Hour Standard

With respect to the requirements under the 1-hour standard, St. Joseph and Elkhart Counties were an attainment area subject to a Clean Air Act section 175A maintenance plan under the 1-hour standard. The Court's ruling does not impact redesignation requests for these types of areas.

First, there are no conformity requirements that are relevant for redesignation requests for any standard, including the requirement to submit a transportation conformity SIP.[3] Under longstanding EPA policy, EPA believes that it is reasonable to interpret the conformity SIP requirement as not applying for purposes of evaluating a redesignation request under section 107(d) because state conformity rules are still required after redesignation and Federal conformity rules apply where state rules have not been approved. 40 CFR 51.390. See *Wall* v. *EPA*, 265 F.3d 426 (6th Cir. 2001), upholding this interpretation. See also 60 FR 62748 (Dec. 7, 1995) (Tampa, FL redesignation). Federal transportation conformity regulations apply in all States prior to approval of transportation conformity SIPs. The one-hour ozone areas in Indiana were redesignated to attainment without approved State Transportation Conformity regulations because the Federal Regulations were in effect in Indiana. When challenged, these 1-hour ozone redesignations, which were approved without State regulations, were upheld by the courts. See *Wall* v. *EPA*, 265 F.3d 426 (6th Cir. 2001). See also 60 FR 62748 (December 7, 1995) (Tampa, Florida). Although Indiana does not have approved State transportation conformity regulations, Indiana has developed memorandums of understanding to address conformity consultation procedures which have been signed by all parties involved in conformity. The Federal transportation conformity regulations, which apply in Indiana, require the approved 1-hour ozone budgets to be used for transportation conformity purposes prior to 8-hour ozone budgets being approved.

Second, with respect to the three other anti-backsliding provisions for the 1-hour standard that the Court found were not properly retained, St. Joseph and Elkhart Counties are an attainment area subject to a maintenance plan for the 1-hour standard, and the NSR, contingency measure (pursuant to section 172(c)(9) or 182(c)(9)) and fee provision requirements no longer apply to an area that has been redesignated to attainment of the 1-hour standard.

Thus the decision in *South Coast* should not alter requirements that would preclude EPA from finalizing the redesignation of this area.

III. What Are the Criteria for Redesignation to Attainment?

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation provided that: (1) The Administrator determines that the area has attained the applicable NAAQS; (2) the Administrator has fully approved an applicable state implementation plan for the area under section 110(k) of the CAA; (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable emission reductions resulting from implementation of the applicable SIP, Federal air pollution control regulations, and other permanent and enforceable emission reductions; (4) the Administrator has fully approved a maintenance plan for the area meeting the requirements of section 175A of the CAA; and, (5) the state containing the area has met all requirements applicable to the area under section 110 and part D of the CAA.

EPA provided guidance on redesignations in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990 on April 16, 1992 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). The two main policy guidelines affecting the review of ozone redesignation requests are the following: ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (September 4, 1992 Calcagni memorandum); and, ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,''

[3] Clean Air Act section 176(c)(4)(E) currently requires States to submit revisions to their SIPs to reflect certain Federal criteria and procedures for determining transportation conformity. Transportation conformity SIPs are different from the motor vehicle emissions budgets that are established in control strategy SIPs and maintenance plans.

Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995. For additional policy guidelines used in the review of ozone redesignation requests, see our proposed rule for the redesignation of the Evansville, Indiana ozone nonattainment area at 70 FR 53606 (September 9, 2005).

IV. What Are EPA's Analyses of the State's Requests and What Are the Bases for EPA's Proposed Action?

EPA is proposing to: (1) Determine that St. Joseph and Elkhart Counties have attained the 8-hour ozone standard; (2) approve the ozone maintenance plan for St. Joseph and Elkhart Counties and the VOC and NO_X MVEBs supported by this maintenance plan; and, (3) approve the redesignation of St. Joseph and Elkhart Counties to attainment of the 8-hour ozone NAAQS. The bases for our proposed determination and approvals follow.

A. St. Joseph and Elkhart Counties Have Attained the 8-Hour Ozone NAAQS

For ozone, an area may be considered to be attaining the 8-hour ozone NAAQS if there are no violations of the NAAQS, as determined in accordance with 40 CFR 50.10 and appendix I, based on the most recent three complete, consecutive calendar years of quality-assured air quality monitoring data at all ozone monitoring sites in the area and in its nearby downwind environs. To attain this standard, the average of the annual fourth-high daily maximum 8-hour average ozone concentrations measured and recorded at each monitor (the monitoring site's ozone design value) within the area and in its nearby downwind environs over the three-year period must not exceed the ozone standard. Based on an ozone data rounding convention described in 40 CFR part 50, appendix I, the 8-hour standard is attained if the area's ozone design value[4] is 0.084 ppm (84 ppb) or lower. The data must be collected and quality-assured in accordance with 40 CFR part 58, and must be recorded in EPA's Air Quality System (AQS). The ozone monitors generally should have remained at the same locations for the duration of the monitoring period required to demonstrate attainment (for three years or more). The data supporting attainment of the standard must be complete in accordance with 40 CFR part 50, appendix I.

As part of the May 30, 2006, ozone redesignation request, IDEM submitted ozone monitoring data indicating the top four daily maximum 8-hour ozone concentrations for each monitoring site in St. Joseph County (the Potato Creek, Harris Township and South Bend ozone monitoring sites) and Elkhart County (the Bristol ozone monitoring site) for each year during the 2003–2005 period. These worst-case ozone concentrations are part of the quality-assured ozone data that have been entered into EPA's AQS. The annual fourth-high 8-hour daily maximum ozone concentrations, along with their three-year averages are summarized in Table 1.

TABLE 1.—FOURTH-HIGH 8-HOUR OZONE CONCENTRATIONS

[In parts per billion (ppb)]

County	Monitoring site	2003	2004	2005	Average
Elkhart	Bristol	87	77	86	83
St. Joseph	Potato Creek	81	73	78	77
St. Joseph	Harris Twp	86	76	86	83
St. Joseph	South Bend	82	72	84	79

These data show that the average fourth-high daily maximum 8-hour ozone concentrations for the monitoring sites in St. Joseph and Elkhart Counties are all below the 85 ppb ozone standard violation cut-off. The data support the conclusion that St. Joseph and Elkhart Counties did not experience a monitored violation of the 8-hour ozone standard from 2003–2005. In addition, the surrounding counties in Indiana and Michigan did not monitor nonattainment during the 2003–2005 period.

We also note that the 8-hour ozone NAAQS continued to be attained in St. Joseph and Elkhart as well as the surrounding counties through 2006. Data in the AQS show that, in 2006, the Bristol, Potato Creek, Harris TWP and South Bend monitors recorded daily maximum fourth-high 8-hour ozone concentrations of 67 ppb, 70 ppb, 70 ppb, and 61 ppb, respectively.

The State has committed to continue ozone monitoring in this area during the maintenance period, through 2020. IDEM commits to consult with the EPA prior to making any changes in the existing monitoring network. An adequate demonstration has therefore been made that St. Joseph and Elkhart Counties have attained the 8-hour ozone NAAQS. Therefore, we propose to find that St. Joseph and Elkhart Counties have attained the 8-hour ozone standard.

B. St. Joseph and Elkhart Counties Have Met All Applicable Requirements Under Section 110 and Part D of the CAA and the Area Has a Fully Approved SIP Under Section 110(k) of the CAA

EPA has determined that Indiana has met all currently applicable SIP requirements for St. Joseph and Elkhart Counties under section 110 of the CAA (general SIP requirements). EPA has determined that the Indiana SIP meets currently applicable SIP requirements under part D of title I of the CAA (requirements specific to basic and subpart 2 ozone nonattainment areas). See section 107(d)(3)(E)(v) of the CAA. In addition, EPA has determined that the Indiana SIP is fully approved with respect to all applicable requirements. See section 107(d)(3)(E)(ii) of the CAA. In making these determinations, EPA ascertained what requirements are applicable to the area, and determined that the applicable portions of the SIP meeting these requirements are fully approved under section 110(k) of the CAA. We note that SIPs must be fully approved only with respect to currently applicable requirements of the CAA, those CAA requirements applicable to St. Joseph and Elkhart Counties at the time the State submitted the final, complete ozone redesignation request for this area.

1. St. Joseph and Elkhart Counties Have Met All Applicable Requirements Under Section 110 and Part D of the CAA

The September 4, 1992, Calcagni memorandum describes EPA's

[4] The worst-case monitoring site-specific ozone design value in the area or in its affected downwind environs.

interpretation of section 107(D)(3)(E) of the CAA. Under this interpretation, to qualify for redesignation of an area to attainment, the State and the area must meet the relevant CAA requirements that come due prior to the State's submittal of a complete redesignation request for the area. See also a September 17, 1993, memorandum from Michael Shapiro, Acting Assistant Administrator for Air and Radiation, ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992'' and 66 FR 12459, 12465–12466 (March 7, 1995) (redesignation of Detroit-Ann Arbor, Michigan to attainment of the 1-hour ozone NAAQS). Applicable requirements of the CAA that come due subsequent to the State's submittal of a complete redesignation request remain applicable until a redesignation to attainment of the standard is approved, but are not required as a prerequisite to redesignation. See section 175A(c) of the CAA. *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). See also 68 FR 25424, 25427 (May 12, 2003) redesignation of the St. Louis/East St. Louis area to attainment of the 1-hour ozone NAAQS.

General SIP requirements: Section 110(a) of title I of the CAA contains the general requirements for a SIP, which include: enforceable emission limitations and other control measures, means, or techniques; provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality; and programs to enforce the emission limitations. SIP elements and requirements are specified in section 110(a)(2) of title I, part A of the CAA. These requirements and SIP elements include, but are not limited to, the following: (a) Submittal of a SIP that has been adopted by the State after reasonable public notice and a hearing; (b) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (c) implementation of a source permit program; (d) provisions for the implementation of new source part C requirements (Prevention of Significant Deterioration (PSD)) and new source part D requirements (New Source Review (NSR)); (e) criteria for stationary source emission control measures, monitoring, and reporting; (f) provisions for air quality modeling; and, (g) provisions for public and local agency participation.

SIP requirements and elements are discussed in the following EPA documents: ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992; ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator, September 17, 1993.

Section 110(a)(2)(D) of the CAA requires SIPs to contain certain measures to prevent sources in one state from significantly contributing to air quality problems in another state. To implement this provision, EPA required states to establish programs to address transport of air pollutants (NO_X SIP call, Clean Air Interstate Rule (CAIR)). EPA has also found, generally, that states have not submitted SIPs under section 110(a)(1) of the CAA to meet the interstate transport requirements of section 110(a)(2)(D)(i) of the CAA (70 FR 21147, April 25, 2005). However, the section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's classification. EPA believes that the requirements linked with a particular nonattainment area's classification are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state.

These requirements should not be construed to be applicable requirements for purposes of redesignation. In addition, the other section 110 elements described above that are not connected with nonattainment plan submissions and that are not linked with an area's attainment status are also not applicable requirements for purposes of redesignation. A state remains subject to these requirements after an area is redesignated to attainment. We conclude that only the section 110 and part D requirements which are linked with an area's designation and classification are the relevant measures in evaluating this aspect of a redesignation request. This approach is consistent with EPA's existing policy on applicability of conformity and oxygenated fuels requirements for redesignation purposes, as well as with section 184 ozone transport requirements. See: Reading, Pennsylvania proposed and final rulemakings (61 FR 53174–53176, October 10, 1996 and 62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida final rulemaking (60 FR 62748, December 7, 1995). See also the discussion on this issue in the Cincinnati, Ohio ozone redesignation (65 FR 37890, June 19, 2000), and the Pittsburgh, Pennsylvania ozone redesignation (66 FR 50399, October 19, 2001). In addition, Indiana's response to the CAIR rule was due in September 2006. Because this deadline had not yet passed when the State submitted the final, complete redesignation request, the State's CAIR submittal is also not an applicable requirement for redesignation purposes.

It should be noted that section 110 elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. Nonetheless, we also note that EPA has previously approved provisions in the Indiana SIP addressing section 110 elements under the 1-hour ozone standard. We have analyzed the Indiana SIP as codified in 40 CFR part 52, subpart P and have determined that it is consistent with the requirements of section 110(a)(2) of the CAA. The SIP, which has been adopted after reasonable public notice and hearing, contains enforceable emission limitations; requires monitoring, compiling, and analyzing ambient air quality data; requires preconstruction review of new major stationary sources and major modifications of existing sources; provides for adequate funding, staff, and associated resources necessary to implement its requirements; and requires stationary source emissions monitoring and reporting, and otherwise satisfies the applicable requirements of section 110(a)(2).

Part D SIP requirements: EPA has determined that the Indiana SIP meets applicable SIP requirements under part D of the CAA. Under part D, an area's classification (marginal, moderate, serious, severe, and extreme) indicates the requirements to which it will be subject. Subpart 1 of part D, found in sections 172–176 of the CAA, sets forth the basic nonattainment area plan requirements applicable to all nonattainment areas. Subpart 2 of part D, found in section 182 of the CAA, establishes additional specific requirements depending on the area's nonattainment classification.

Part D, subpart 1 requirements: For purposes of evaluating this redesignation request, the applicable subpart 1 part D requirements for all nonattainment areas are contained in sections 172(c)(1)-(9) and 176. A thorough discussion of the requirements of section 172 can be found in the General Preamble for Implementation of Title I (57 FR 13498). (See also 68 FR 4852–4853 regarding a St. Louis ozone redesignation notice of proposed rulemaking for a discussion of section 172 requirements.)

No requirements under part D of the CAA came due for St. Joseph and Elkhart Counties prior to the State's May 30, 2006, submittal of a complete redesignation request. For example, the requirement for an ozone attainment demonstration, as contained in section 172(c)(1), was not yet applicable, nor were the requirements for Reasonably Available Control Measures (RACM) and Reasonably Available Control Technology (RACT) (section 172(c)(1)), Reasonable Further Progress (RFP) (section 172(c)(2)), and attainment plan and RFP contingency measures (section 172(c)(9)). All of these required SIP elements are required for submittal after May 30, 2006. Therefore, none of the part D requirements are applicable to St. Joseph and Elkhart Counties for purposes of redesignation.

Section 176 conformity requirements: Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally-supported or funded activities, including highway projects, conform to the air planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects developed, funded, or approved under Title 23 U.S.C. and the Federal Transit Act (transportation conformity) as well as to all other Federally-supported or funded projects (general conformity). State conformity SIP revisions must be consistent with Federal conformity regulations that the CAA required the EPA to promulgate.

In addition to the fact that part D requirements did not become due prior to Indiana's submission of the complete ozone redesignation request for St. Joseph and Elkhart Counties, and, therefore, are not applicable for redesignation purposes, EPA has similarly concluded that the conformity requirements do not apply for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA. In addition, it is reasonable to interpret the conformity requirements as not applying for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA because state conformity rules are still required after redesignation of an area to attainment of a NAAQS and Federal conformity rules apply where state rules have not been approved. See *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001). See also 60 FR 62748 (December 7, 1995) (Tampa, Florida).

We conclude that the State and St. Joseph and Elkhart Counties have satisfied all applicable requirements under section 110 and part D of the CAA to the extent that the requirements apply for the purposes of reviewing the State's ozone redesignation request.

2. St. Joseph and Elkhart Counties Have a Fully Approved Applicable SIP Under Section 110(k) of the CAA

EPA has fully approved the Indiana SIP for St. Joseph and Elkhart Counties under section 110(k) of the CAA for all applicable requirements. EPA may rely on prior SIP approvals in approving a redesignation request (See the September 4, 1992 John Calcagni memorandum, page 3, *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–990 (6th Cir. 1998), *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001)), plus any additional measures it may approve in conjunction with a redesignation action. See 68 FR 25426 (May 12, 2003). Since the passage of the CAA of 1970, Indiana has adopted and submitted, and EPA has fully approved, provisions addressing the various required SIP elements applicable to St. Joseph and Elkhart Counties for purposes of redesignation. No St. Joseph and Elkhart Counties SIP provisions are currently disapproved, conditionally approved, or partially approved. As indicated above, EPA believes that the section 110 elements not connected with nonattainment plan submissions and not linked to the area's nonattainment status are not applicable requirements for purposes of review of the State's redesignation request. EPA has concluded that the section 110 SIP submission approved under the 1-hour standard will be adequate for purposes of attaining and maintaining the 8-hour standard. EPA also believes that since the part D requirements did not become due prior to Indiana's submission of a final, complete redesignation request, they also are not applicable requirements for purposes of redesignation.

C. The Air Quality Improvement in St. Joseph and Elkhart Counties Is Due to Permanent and Enforceable Reductions in Emissions From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Emission Reductions

EPA believes that the State of Indiana has demonstrated that the observed air quality improvement in St. Joseph and Elkhart Counties is due to permanent and enforceable emission reductions resulting from implementation of the SIP, Federal measures, and other State-adopted measures.

In making this demonstration, the State has documented the changes in VOC and NO_X emissions from anthropogenic (man-made or man-based) sources in St. Joseph and Elkhart Counties between 1996 and 2004 and the statewide NO_X emissions from Electric Generating Units (EGUs) from 1999 to 2005. St. Joseph and Elkhart Counties were monitored in violation of the 8-hour ozone NAAQS during the period of 1997 through 1999 and in attainment with the NAAQS during the period of 2003 through 2005. The total VOC and NO_X emissions for St. Joseph and Elkhart Counties for various years during the period of 1996 through 2004 are given in Table 2.

TABLE 2.—VOC AND NO_X EMISSIONS IN ST. JOSEPH AND ELKHART COUNTIES, ALL SOURCES

[Emissions in tons/summer day]

Pollutant	1996	1999	2002	2004
VOC	127.88	113.82	89.18	85.98
NO_X	91.21	74.63	63.4	63.16

The statewide NO_X emissions for EGUs from 1999–2005 are given in Table 3. below.

TABLE 3.—NO_X EMISSIONS FROM ELECTRIC GENERATING UNITS IN INDIANA STATEWIDE

[Emissions in thousands of tons per ozone season (April–October)]

Area	1999	2000	2001	2002	2003	2004	2005
Statewide	149.8	133.9	136.1	114.0	99.3	66.6	55.5

The NO_X and VOC emissions for St. Joseph and Elkhart Counties and the statewide EGU NO_X emissions have decreased from 1999, an 8-hour standard violation years, to 2004 and 2005 (for EGUs), attainment years. IDEM notes that statewide NO_X emissions have declined significantly as a result of the implementation of the Indiana NO_X SIP (in response to EPA's NO_X SIP call) and acid rain control regulations, both of which led to permanent, enforceable emission reductions.

VOC and NO_X emissions have declined between 1999 and 2004 as a result of enforceable emission reductions. As required by Section 172 of the CAA, Indiana in the mid-1990s promulgated rules requiring RACT for emissions of VOCs. Statewide RACT rules have applied to all new sources locating in Indiana since that time and include the following VOC rules: 326 Indiana Administrative Code (IAC) 8–1–6 (Best Available Control Technology (BACT) for non-specific sources); 326 IAC 8–2 (surface coating emission limitations); 326 IAC (organic solvent degreasing operations); 326 IAC 8–4 (petroleum sources); and, 326 IAC 8–5 (miscellaneous sources). The VOC emission reductions resulting from the implementation of these VOC emission control rules are permanent and enforceable.

Besides the statewide VOC RACT rules and NO_X emission control requirements, other Federal emission reduction requirements have resulted in decreased ozone precursor emissions in St. Joseph and Elkhart Counties and will produce future emission reductions that will support maintenance of the ozone standard in St. Joseph and Elkhart Counties. These emission reduction requirements include the following:

Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards. These emission control requirements result in lower emissions from new cars and light duty trucks, including sport utility vehicles. The Federal rules are being phased in between 2004 and 2009. The EPA has estimated that, by the end of the phase-in period, the following vehicle NO_X emission reductions will occur: passenger cars (light duty vehicles) (77 percent); light duty trucks, minivans, and sports utility vehicles (86 percent; and larger sports utility vehicles, vans, and heavier trucks (69 to 95 percent). VOC emission reductions are also expected to range from 12 to 18 percent, depending on vehicle class, over the same period. Although some of these emission reductions have already occurred by the 2004 attainment year, most of these emission reductions will occur during the maintenance period for St. Joseph and Elkhart Counties.

Heavy-Duty Diesel Engines. In July 2000, EPA issued a final rule to control the emissions from highway heavy duty diesel engines, including low-sulfur diesel fuel standards. These emission reductions are being phased in between 2004 and 2007. This rule is expected to result in a 40 percent decrease in NO_X emissions from heavy duty diesel vehicle.

Non-Road Diesel Rule. Issued in May, 2004, this rule generally applies to new stationary diesel engines used in certain industries, including construction, agriculture, and mining. In addition to affecting engine design, this rule includes requirements for cleaner fuels. This rule is expected to reduce NO_X emissions from these engines by up to 90 percent, and to significantly reduce particulate matter and sulfur emissions from these engines in addition to the NO_X emission reduction. This rule did not affect 2004 emissions from these sources, but will limit emissions from new engines beginning in 2008.

Indiana commits to maintain all existing emission control measures that affect St. Joseph and Elkhart Counties after this area is redesignated to attainment of the 8-hour ozone NAAQS. All changes in existing rules affecting St. Joseph and Elkhart Counties and new rules subsequently needed to provide for the maintenance of the 8-hour ozone NAAQS in St. Joseph and Elkhart Counties will be submitted to the EPA for approval as SIP revisions.

D. St. Joseph and Elkhart Counties Have a Fully Approvable Ozone Maintenance Plan Pursuant to Section 175A of the CAA

In conjunction with its request to redesignate St. Joseph and Elkhart Counties to attainment of the ozone NAAQS, Indiana submitted a SIP revision request to provide for maintenance of the 8-hour ozone NAAQS in St. Joseph and Elkhart Counties for at least 10 years after the redesignation of this area to attainment of the 8-hour ozone NAAQS.

1. What Is Required in an Ozone Maintenance Plan?

Section 175A of the CAA sets forth the required elements of air quality maintenance plans for areas seeking redesignation from nonattainment to attainment of a NAAQS. Under section 175A, a maintenance plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after the Administrator approves the redesignation to attainment. Eight years after the redesignation, the State must submit a revised maintenance plan which demonstrates maintenance of the standard for 10 years following the initial 10 year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary, to assure prompt correction of any future NAAQS violations. The September 4, 1992, John Calcagni memorandum provides additional guidance on the content of maintenance plans. An ozone maintenance plan should, at minimum, address the following items: (1) The attainment VOC and NO_X emissions inventories; (2) a maintenance demonstration showing maintenance for the 10 years of the maintenance period; (3) a commitment to maintain the existing monitoring network; (4) factors and procedures to be used for verification of continued attainment; and, (5) a contingency plan to prevent and/or correct a future violation of the NAAQS.

2. What Are the Attainment Emission Inventories for St. Joseph and Elkhart Counties?

IDEM prepared comprehensive VOC and NO_X emission inventories for St. Joseph and Elkhart Counties, including point (significant stationary sources), area (smaller and widely-distributed stationary sources), mobile on-road, and mobile non-road sources for 2004 (the base year/attainment year). To develop the attainment year emission inventories, IDEM used the following approaches and sources of data:

Area Sources—Area source VOC and NO_X emissions were projected from Indiana's 2002 periodic emissions inventory, which was previously submitted to the EPA.

Mobile On-Road Sources—Mobile source emissions were calculated using the MOBILE6 emission factor model and traffic data (vehicle miles traveled, vehicle speeds, and vehicle type and age distributions) extracted from the region's travel-demand model.

Point Source Emissions—2004 point source emissions were compiled using IDEM's 2004 annual emissions statement database and the 2005 EPA Air Markets acid rain emissions inventory database.

Mobile Non-Road Emissions—Non-road mobile source emissions were estimated by the EPA and documented in the 2002 National Emissions Inventory (NEI). IDEM used these emissions estimates along with growth factors to grow the non-road mobile source emissions to 2004. To address concerns about the accuracy of some of the emissions for various source categories in EPA's non-road emissions model, the Lake Michigan Air Directors Consortium (LADCO) contracted with several companies to review the base data used by the EPA and to make recommendations for corrections to the model. Emissions were estimated for commercial marine vessels and railroads. Recreational motorboat population and spatial surrogates (used to assign emissions to each county) were updated. The populations for the construction equipment category were reviewed and updated based on surveys completed in the Midwest, and the temporal allocation for agricultural sources was also updated. Based on these and other updates, the EPA provided a revised non-road estimation model, which was used for the 2004 projected non-road mobile source emissions.

The 2004 attainment year VOC and NO_X emissions for St. Joseph and Elkhart Counties are summarized along with the 2010 and 2020 projected emissions for these counties in Tables 4 and 5, below. They confirm that the State has acceptably derived and documented the attainment year VOC and NO_X emissions for St. Joseph and Elkhart Counties.

3. Demonstration of Maintenance

As part of the May 30, 2006, redesignation request submittal, IDEM included a requested revision to the SIP to incorporate a 13-year ozone maintenance plan which is consistent with the requirements under section 175A of the CAA. Included in the maintenance plan is a maintenance demonstration. This demonstration shows maintenance of the 8-hour ozone NAAQS by documenting current and projected VOC and NO_X emissions and by documenting photochemical modeling results that support maintenance of the standard in this area.[5]

Table 4 specifies the VOC emissions in St. Joseph and Elkhart Counties for 2004, 2010, and 2020. IDEM chose 2020 as a projection year to meet the 10-year minimum maintenance projection requirement, allowing several years for the State to complete its adoption of the ozone redesignation request and ozone maintenance plan and for the EPA to approve the redesignation request and maintenance plan. IDEM also chose 2010 as an interim year to demonstrate that VOC and NO_X emissions will remain below the attainment levels throughout the 10-year maintenance period.

Table 5, similar to Table 4, specifies the NO_X emissions in St. Joseph and Elkhart Counties for 2004, 2010, and 2020. Together, Tables 4 and 5 and the photochemical modeling results demonstrate that St. Joseph and Elkhart Counties should remain in attainment of the 8-hour ozone NAAQS between 2004 and 2020, for more than 10 years after EPA is expected to approve the redesignation of St. Joseph and Elkhart Counties to attainment of the 8-hour ozone NAAQS.

TABLE 4.—ATTAINMENT YEAR (2004) AND PROJECTED VOC EMISSIONS IN ST. JOSEPH AND ELKHART COUNTIES

[Tons per summer day]

Source sector	Year		
	2004	2010	2020
Point	25.63	29.16	39.78
Area	29.43	31.15	35.20
On-Road Mobile	17.52	11.56	6.64
Off-Road Mobile	13.40	10.47	8.06
Total	85.98	82.34	89.68

TABLE 5.—ATTAINMENT YEAR AND PROJECTED NO_X EMISSIONS IN ST. JOSEPH AND ELKHART COUNTIES

[Tons per summer day]

Source sector	Year		
	2004	2010	2020
Point	6.36	6.32	7.17
Area	7.13	7.54	7.98
On-Road Mobile	30.11	19.29	7.73
Off-Road Mobile	19.56	14.06	9.78
Total	63.16	47.21	32.66

[5] The attainment year can be any of the three consecutive years in which the area has clean (below violation level) air quality data (2003, 2004, or 2005 for St. Joseph and Elkhart Counties).

IDEM also notes that the State's EGU NO_X emission control rules stemming from EPA's NO_X SIP call, implemented beginning in 2004, and CAIR will further lower NO_X emissions in upwind areas, resulting in decreased ozone and ozone precursor transport into St. Joseph and Elkhart Counties (the State did not project the emission decreases resulting from CAIR and did not document future NO_X emissions in upwind Counties). This will also support maintenance of the ozone standard in St. Joseph and Elkhart Counties.

Based upon the data in Table 5, NO_X emissions in St. Joseph and Elkhart Counties are projected to decline by more than 48% between 2004 and 2020, but VOC emissions are projected to increase by a modest 4.3% during that period. This slight increase in VOC emissions, however, is more than offset by the significant local and regional decreases in NO_X emissions to occur during the same timeframe. This offsetting of an increase in VOC emissions with NO_X emission reductions is consistent with EPA's December 1993 NO_X Substitution Policy (which specifies that a percentage basis, rather than a mass basis, is used for equivalency calculations) which was transmitted under cover of a December 15, 1993, memorandum from John Seitz, (then) Director, Office of Air Quality Planning and Standards, as clarified in an August 5, 1994, memorandum also from John Seitz, titled ''Clarification of Policy for Nitrogen Oxides Substitution.'' As discussed in Indiana's submittal, EPA modeling shows that existing national emission control measures have brought St. Joseph and Elkhart Counties into attainment of the 8-hour NAAQS. Rulemakings to be implemented in the next several years will provide even greater assurance that air quality will continue to meet the standard in the future. Modeling for the NO_X SIP call, Heavy Duty Engine Rule, Highway Diesel Fuel and Tier II/Low Sulfur Fuel Rule, and CAIR shows that future year design values for St. Joseph and Elkhart Counties through 2020 will continue to show attainment of the ozone standard, with modeled future ozone design values well below 0.085 ppm.

Based on the comparison of the projected emissions and the attainment year emissions, and photochemical modeling results, we conclude that IDEM has successfully demonstrated that the 8-hour ozone standard should be maintained in St. Joseph and Elkhart Counties. We believe that this is especially likely given the expected impacts of the NO_X SIP call and CAIR. As noted by IDEM, this conclusion is further supported by the fact that other states in the eastern portion of the United States are expected to further reduce regional NO_X emissions through implementation of their own NO_X emission control rules for EGUs and other NO_X sources and through implementation of CAIR, reducing ozone and NO_X transport into St. Joseph and Elkhart Counties.

4. Monitoring Network

IDEM commits to continue operating and maintaining an approved ozone monitoring network in St. Joseph and Elkhart Counties in accordance with 40 CFR part 58 through the 13-year maintenance period. This will allow the confirmation of the maintenance of the 8-hour ozone standard in this area and the triggering of contingency measures if needed.

5. Verification of Continued Attainment

Continued attainment of the 8-hour ozone NAAQS in St. Joseph and Elkhart Counties depends on the State's efforts toward tracking applicable indicators during the maintenance period. The State's plan for verifying continued attainment of the 8-hour ozone standard in St. Joseph and Elkhart Counties consists, in part, of a plan to continue ambient ozone monitoring in accordance with the requirements of 40 CFR part 58. In addition, IDEM will periodically revise and review the VOC and NO_X emissions inventories for St. Joseph and Elkhart Counties to assure that emissions growth is not threatening the continued attainment of the 8-hour ozone standard in this area. Revised emission inventories for this area will be prepared for 2005, 2008, and 2011 as necessary to comply with the emission inventory reporting requirements established in the CAA. The revised emissions will be compared with the 2004 attainment emissions and the 2020 projected maintenance year emissions to assure continued maintenance of the ozone standard.

6. Contingency Plan

The contingency plan provisions of the CAA are designed to result in prompt correction or prevention of violations of the NAAQS that might occur after redesignation of an area to attainment of the NAAQS. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the State will promptly correct a violation of the NAAQS that might occur after redesignation. The maintenance plan must identify the contingency measures to be considered for possible adoption, a schedule and procedure for adoption and implementation of the selected contingency measures, and a time limit for action by the State. The State should also identify specific indicators to be used to determine when the contingency measures need to be adopted and implemented. The maintenance plan must include a requirement that the State will implement all measures with respect to control of the pollutant(s) that were controlled in the SIP before the redesignation of the area to attainment. See section 175A(d) of the CAA.

As required by section 175A of the CAA, Indiana commits to review its Maintenance Plan eight years after redesignation and to adopt and expeditiously implement any necessary corrective actions (or contingency measures). Contingency measures to be considered will be selected from a comprehensive list of measures deemed appropriate and effective at the time the selection is made. The contingency plan has two levels of actions/responses depending on whether a violation of the 8-hour ozone standard is only threatened (Warning Level Response) or has actually occurred (Action Level Response).

A Warning Level Response will be prompted whenever an annual (1-year) fourth-high monitored daily peak 8-hour ozone concentration of 89 ppb (or greater) occurs at any monitor in St. Joseph and Elkhart Counties, or a 2-year averaged annual fourth-high daily peak 8-hour ozone concentration of 85 ppb or greater occurs at any monitor in St. Joseph and Elkhart Counties. A Warning Level Response will consist of a study to determine whether the monitored ozone level indicates a trend toward higher ozone levels or whether emissions are increasing, threatening a future violation of the ozone NAAQS. The study will evaluate whether the trend, if any, is likely to continue, and, if so, the emission control measures necessary to reverse the trend, taking into consideration the ease and timing of implementation, as well as economic and social considerations. Implementation of necessary controls will take place as expeditiously as possible, but in no event later than 12 months from the conclusion of the most recent ozone season. If new emission controls are needed to reverse the adverse ozone trend, the procedures for emission control selection under the Action Level Response will be followed.

An Action Level Response will be triggered when a violation of the 8-hour ozone standard is monitored at any of the monitors in St. Joseph and Elkhart

Counties (when a 3-year average annual fourth-high monitored daily peak 8-hour ozone concentration of 85 ppb or higher is recorded at any monitor in St. Joseph and Elkhart Counties). In this situation, IDEM will determine the additional emission control measures needed to assure future attainment of the 8-hour ozone NAAQS. IDEM will focus on emission control measures that can be implemented within 18 months from the close of the ozone season in which the ozone standard violation is monitored.

Adoption of any additional emission control measures prompted by either of the two response levels will be subject to the necessary administrative and legal processes dictated by State law. This process will include publication of public notices, providing the opportunity for a public hearing, and other measures required by Indiana law for rulemaking by State environmental boards. If a new emission control measure is already promulgated and scheduled for implementation at the Federal or State level, and that emission control measure is determined to be sufficient to address the air quality problem or adverse trend, additional local emission control measures may be determined to be unnecessary. IDEM will submit to the EPA an analysis to demonstrate that the proposed emission control measures or existing emission control measures are adequate to provide for future attainment of the 8-hour ozone NAAQS in St. Joseph and Elkhart Counties.

Contingency measures contained in the maintenance plan are those emission controls or other measures that the State may choose to adopt and implement to correct existing or possible air quality problems in St. Joseph and Elkhart Counties. These include, but are not limited to, the following:

i. Lower Reid vapor pressure gasoline requirements;

ii. Broader geographic applicability of existing emission control measures;

iii. Tightened RACT requirements on existing sources covered by EPA Control Technique Guidelines (CTGs) issued in response to the 1999 CAA amendments;

iv. Application of RACT to smaller existing sources;

v. Vehicle Inspection and Maintenance (I/M);

vi. One or more Transportation Control Measure (TCM) sufficient to achieve at least a 0.5 percent reduction in actual area-wide VOC emissions, to be selected from the following:

A. Trip reduction programs, including, but not limited to, employer-based transportation management plans, area-wide rideshare programs, work schedule programs, and telecommuting;

B. Transit improvement;

C. Traffic flow improvements; and,

D. Other new or innovative transportation measures not yet in widespread use that affect State and local governments as deemed appropriate;

vii. Alternative fuel and diesel retrofit programs for fleet vehicle operations;

viii. Controls on consumer products consistent with those adopted elsewhere in the United States;

ix. VOC or NO_X emission offsets for new or modified major sources;

x. VOC or NO_X emission offsets for new or modified minor sources;

xi. Increased ratio of emission offsets required for new sources; and,

xii. VOC or NO_X emission controls on new minor sources (with VOC or NO_X emissions less than 100 tons per year).

7. Provisions for a Future Update of the Ozone Maintenance Plan

As required by section 175A(b) of the CAA, the State commits to submit to the EPA an update of the ozone maintenance plan eight years after redesignation of the Counties to attainment of the 8-hour ozone NAAQS. The revision will contain Indiana's plan for maintaining the 8-hour ozone standard for 10 years beyond the first 10-year period after redesignation.

V. Has Indiana Adopted Acceptable Motor Vehicle Emissions Budgets for the End of the 14-Year Maintenance Plan Which Can Be Used To Support Transportation Conformity Determinations?

A. How Are the Motor Vehicle Emission Budgets Developed and What Are the Motor Vehicle Emission Budgets for St. Joseph and Elkhart Counties?

Under the CAA, states are required to submit, at various times, SIP revisions and ozone maintenance plans for applicable areas (for ozone nonattainment areas and for areas seeking redesignations to attainment of the ozone standard or revising existing ozone maintenance plans). These emission control SIP revisions (e.g., reasonable further progress and attainment demonstration SIP revisions), including ozone maintenance plans, must create MVEBs based on on-road mobile source emissions allocated to highway and transit vehicle use that, together with emissions from other sources in the area, will provide for attainment or maintenance of the ozone NAAQS.

Under 40 CFR part 93, MVEBs for an area seeking a redesignation to attainment of the NAAQS are established for the last year of the maintenance plan. The MVEBs serve as ceilings on emissions from an area's planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEBs in the SIP and how to revise the MVEBs if needed.

Under section 176(c) of the CAA, new transportation projects, such as the construction of new highways, must ''conform'' to (*i.e.*, be consistent with) the part of the SIP that addresses emissions from cars and trucks. Conformity to the SIP means that transportation activities will not cause new air quality standard violations, or delay timely attainment of the NAAQS. If a transportation plan does not conform, most new transportation projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA's policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities to a SIP.

When reviewing SIP revisions containing MVEBs, including attainment strategies, rate-of-progress plans, and maintenance plans, EPA must affirmatively find that the MVEBs are ''adequate'' for use in determining transportation conformity. Once EPA affirmatively finds the submitted MVEBs to be adequate for transportation conformity purposes, the MVEBs are used by state and Federal agencies in determining whether proposed transportation projects conform to the SIPs as required by section 176(c) of the CAA. EPA's substantive criteria for determining the adequacy of MVEBs are specified in 40 CFR 93.118(e)(4).

EPA's process for determining adequacy of MVEBs consists of three basic steps: (1) Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEBs during a public comment period; and, (3) making a finding of adequacy. The process of determining the adequacy of submitted SIP MVEBs was initially outlined in EPA's May 14, 1999, guidance, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.'' This guidance was finalized in the Transportation Conformity Rule Amendments for the ''New 8-Hour Ozone and PM2.5 National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas: Transportation Conformity Rule Amendments—Response to Court

Decision and Additional Rule Change'' published on July 1, 2004 (69 FR 40004). EPA follows this guidance and rulemaking in making its adequacy determinations.

The Transportation Conformity Rule, in 40 CFR section 93.118(f), provides for MVEB adequacy findings through two mechanisms. First, 40 CFR 93.118(f)(1) provides for posting a notice to the EPA conformity Web site at: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm* and providing a 30-day public comment period. Second, a mechanism is described in 40 CFR 93.118(f)(2) which provides that EPA can review the adequacy of an implementation plan MVEB simultaneously with its review of the implementation plan itself.

The St. Joseph and Elkhart Counties 14-year maintenance plan contains VOC and NO_X MVEBs for 2020. EPA has reviewed the submittal and the VOC and NO_X MVEBs for St. Joseph and Elkhart Counties and finds that the MVEBs meet the adequacy criteria in the Transportation Conformity Rule. The 30-day comment period for adequacy will be the same as the comment period for approval of the budgets and maintenance plan. Any and all comments on the adequacy or approvability of the budgets should be submitted during the comment period stated in the **DATES** section of this notice.

EPA, through this rulemaking, is proposing to approve the MVEBs for use to determine transportation conformity in St. Joseph and Elkhart Counties because EPA has determined that the budgets are consistent with the control measures in the SIP and that St. Joseph and Elkhart Counties can maintain attainment of the 8-hour ozone NAAQS for the relevant required 13-year period with mobile source emissions at the levels of the MVEBs. IDEM has determined the 2020 MVEBs for St. Joseph and Elkhart Counties to be 6.64 tons per day for VOC and 7.73 tons per day for NO_X.

B. Are the MVEBs Approvable?

The VOC and NO_X MVEBs for St. Joseph and Elkhart Counties are approvable because they provide for continued maintenance of the 8-hour ozone standard through 2020.

VI. What Is the Effect of EPA's Proposed Action?

Approval of the redesignation request would change the official designation of St. Joseph and Elkhart Counties for the 8-hour ozone NAAQS, found at 40 CFR part 81, from nonattainment to attainment. It would also incorporate into the Indiana SIP a plan for maintaining the ozone NAAQS through 2020. The maintenance plan includes contingency measures to remedy possible future violations of the 8-hour ozone NAAQS, and establishes MVEBs of 6.64 tons per day for VOC and 7.73 tons per day for NO_X.

VII. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, September 30, 1993), this action is not a ''significant regulatory action'' and, therefore, is not subject to review by the Office of Management and Budget.

Paperwork Reduction Act

This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant regulatory action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272, requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impractical. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Clean Air Act. Therefore, the requirements of section 12(d) of the NTTAA do not apply.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

40 CFR Part 81

Air pollution control, Environmental protection, National parks, Wilderness areas.

Dated: April 6, 2007.

Walter W. Kovalick,

Acting Regional Administrator, Region 5.

[FR Doc. E7–7347 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2006–0459; FRL–8301–9]

Determination of Attainment, Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Indiana; Redesignation of the LaPorte County 8-Hour Nonattainment Area to Attainment for Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On May 30, 2006, the Indiana Department of Environmental Management (IDEM) submitted a request for EPA approval of a redesignation of LaPorte County to attainment of the 8-hour ozone National Ambient Air Quality Standard (NAAQS) and of an ozone maintenance plan for LaPorte County as a revision to the Indiana State Implementation Plan (SIP). EPA is proposing to approve Indiana's request and maintenance plan SIP revision. EPA is also proposing to approve the Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Motor Vehicle Emission Budgets (MVEBs) for LaPorte County, as supported by the ozone maintenance plan for this County, for purposes of conformity determinations.

DATES: Comments must be received on or before May 18, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–0459, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: mooney.john@epa.gov.*
- *Fax:* (312) 886–5824.
- *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
- *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois. Such deliveries are only accepted during the Regional Office's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office's official hours of operation are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2006–0459. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through *www.regulations.gov* or e-mail. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and should be free of any defects or viruses

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hardcopy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hardcopy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. It is recommended that you telephone Edward Doty, Environmental Scientist, at (312) 886–6057, before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Edward Doty, Environmental Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6057, *doty.edward@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA. This supplementary information section is arranged as follows:

I. What Action Is EPA Proposing To Take?
II. What Is the Background for This Action?
III. What Are the Criteria for Redesignation to Attainment?
IV. What Are EPA's Analyses of the State's Requests and What Are the Bases for EPA's Proposed Action?
V. Has Indiana Adopted Acceptable Motor Vehicle Emissions Budgets for the End of the 10-Year Maintenance Plan Which Can Be Used To Support Conformity Determinations?
VI. What Is the Effect of EPA's Proposed Action?
VII. Statutory and Executive Order Reviews

I. What Action Is EPA Proposing To Take?

We are proposing to take several related actions for LaPorte County. First, we are proposing to determine that LaPorte County has attained the 8-hour ozone NAAQS based on air quality for the period of 2003 through 2005. Second, we are proposing to approve Indiana's ozone maintenance plan for LaPorte County as a requested revision to the Indiana SIP. The maintenance plan is designed to keep LaPorte County in attainment of the 8-hour ozone standard for the next 14 years, through 2020. As supported by and consistent with the ozone maintenance plan, we are also proposing to approve the 2020 VOC and NO_X MVEBs for LaPorte County for conformity purposes. Finally, we are proposing to approve the request from the State of Indiana to change the designation of LaPorte County from nonattainment to attainment of the 8-hour ozone NAAQS. We have determined that the State and LaPorte County have met the

requirements for redesignation to attainment under section 107(d)(3)(E) of the Clean Air Act (CAA).

II. What Is the Background for This Action?

A. General Background Information

EPA has determined that ground-level ozone is detrimental to human health. On July 18, 1997, EPA promulgated an 8-hour ozone NAAQS of 0.08 parts per million parts of air (0.08 ppm) (80 parts per billion (ppb)) (62 FR 38856).[1] This 8-hour ozone standard replaced a prior 1-hour ozone NAAQS, which had been promulgated on February 8, 1979 (44 FR 8202), and which EPA revoked on June 15, 2005 (69 FR 23858).

Ground-level ozone is not emitted directly by sources. Rather, emitted NO_X and VOC react in the presence of sunlight to form ground-level ozone along with other secondary compounds. NO_X and VOC are referred to as ''ozone precursors.'' Control of ground-level ozone concentrations is achieved through controlling VOC and NO_X emissions.

Section 107 of the CAA required EPA to designate as nonattainment any area that violates the 8-hour ozone NAAQS. The **Federal Register** notice promulgating the 8-hour ozone designations and classifications was published on April 30, 2004 (69 FR 23857).

The CAA contains two sets of provisions—subpart 1 and subpart 2—that address planning and emission control requirements for nonattainment areas. Both are found in title I, part D of the CAA. Subpart 1 contains general, less prescriptive requirements for all nonattainment areas for any pollutant governed by a NAAQS. Subpart 2 contains more specific requirements for certain ozone nonattainment areas, and applies to ozone nonattainment areas classified under section 181 of the CAA.

In the April 30, 2004 designation rulemaking, EPA divided 8-hour ozone nonattainment areas into the categories of subpart 1 nonattainment (''basic'' nonattainment) and subpart 2 nonattainment (''classified'' nonattainment). EPA based this division on the areas 8-hour ozone design values (*i.e.*, on the three-year averages of the annual fourth-highest daily maximum 8-hour ozone concentrations at the worst-case monitoring sites in the areas) and on their 1-hour ozone design values (*i.e.*, on the fourth-highest daily maximum 1-hour ozone concentrations over the three-year period at the worst-case monitoring sites in the areas).[2] EPA classified 8-hour ozone nonattainment areas with 1-hour ozone design values equaling or exceeding 121 ppb as subpart 2, classified nonattainment areas. EPA classified all other 8-hour nonattainment areas as subpart 1, basic nonattainment areas. The basis for area classification was defined in a separate April 30, 2004, final rule (the Phase 1 implementation rule) (69 FR 23951).

Emission control requirements for classified nonattainment areas are linked to area classifications. Areas with more serious ozone pollution problems are subject to more prescribed requirements and later attainment dates. The prescribed emission control requirements are designed to bring areas into attainment by their specified attainment dates.

In the April 30, 2004, ozone designation/classification rulemaking, EPA designated LaPorte County as a subpart 2 moderate nonattainment area for the 8-hour ozone NAAQS. This designation was based on ozone data collected during the 2001–2003 period. On September 22, 2004 (69 FR 56697), EPA revised the designation of LaPorte County to subpart 2 marginal nonattainment.

On May 30, 2006, the State of Indiana requested redesignation of LaPorte County to attainment of the 8-hour ozone NAAQS based on ozone data collected in LaPorte County during the 2003–2005 period. On August 24, 2006, IDEM submitted a summary of an ozone data review and supplementary ozone data to address a shortfall in the data supporting the ozone redesignation request.

B. What Is the Impact of the December 22, 2006 United States Court of Appeals Decision Regarding EPA's Phase 1 Implementation Rule?

On December 22, 2006, the United States Court of Appeals for the District of Columbia Circuit (the Court) vacated EPA's Phase 1 implementation rule (Phase 1 Rule) for the 8-hour ozone standard (69 FR 23951, April 30, 2004). *South Coast Air Quality Management Dist.* v. *EPA,* 472 F.3d 882 (D.C. Cir. 2006). The Court held that certain provisions of EPA's Phase 1 Rule were inconsistent with the requirements of the CAA. The Court rejected EPA's reasons for implementing the 8-hour ozone standard in nonattainment areas under subpart 1 in lieu of subpart 2 of Title I, part D of the CAA. The Court also held that EPA improperly failed to retain four measures required for 1-hour ozone nonattainment areas under the anti-backsliding provisions of the regulations: (1) Nonattainment area New Source Review (NSR) requirements based on an area's 1-hour nonattainment classification; (2) section 185 penalty fees for 1-hour severe or extreme ozone nonattainment areas; (3) measures to be implemented pursuant to section 172(c)(9) or 182(c)(9) of the CAA, on the contingency of an area not making reasonable further progress toward attainment of the 1-hour ozone NAAQS, or failing to attain that NAAQS; and, (4) conformity requirements for certain types of Federal actions. The Court upheld EPA's authority to revoke the 1-hour ozone standard provided that there were adequate anti-backsliding provisions.

This section sets forth EPA's views on the potential effect of the Court's ruling on this redesignation action. For the reasons set forth below, EPA does not believe that the Court's ruling alters any requirements relevant to this redesignation action so as to preclude redesignation, and does not prevent EPA from finalizing this redesignation. EPA believes that the Court's decision, as it currently stands or as it may be modified based on any petition for rehearing that has been filed, imposes no impediment to moving forward with redesignation of this area to attainment, because in either circumstance redesignation is appropriate under the relevant redesignation provisions of the CAA and longstanding policies regarding redesignation requests.

With respect to the 8-hour ozone standard, LaPorte County is classified as moderate nonattainment under subpart 2 of the CAA. We do not believe that any part of the Court's opinion would require that this subpart 2 classification be changed upon remand to EPA. However, even assuming for present purposes that LaPorte County would become subject to a different classification under a classification scheme created in a future rule in response to the Court's decision, this would not prevent EPA from finalizing a redesignation for this area. For the reasons set forth below, we believe that any additional requirements that might apply based on that different classification would not be applicable for purposes of evaluating the redesignation request.

This belief is based on: (1) EPA's longstanding policy of evaluating

[1] This standard is violated in an area when any ozone monitor in the area (or in its impacted downwind environs) records 8-hour ozone concentrations with an average of the annual fourth-highest daily maximum 8-hour ozone concentrations over a three-year period equaling or exceeding 85 ppb. See 40 CFR 50.10.

[2] The 8-hour ozone design value and the 1-hour ozone design value for each area were not necessarily recorded at the same monitoring site. The worst-case monitoring site for each ozone concentration averaging time was considered for each area.

redesignation requests in accordance with only the requirements due at the time the complete redesignation request was submitted; and, (2) consideration of the inequity of retroactively applying any requirements that might be applied in the future.

First, at the time the complete redesignation request was submitted (May 30, 2006), LaPorte County was classified under subpart 2 and was required to meet the subpart 2 requirements. Under EPA's longstanding interpretation of section 107(d)(3)(E) of the CAA, to qualify for redesignation, states requesting redesignation to attainment must meet only the relevant SIP requirements that came due prior to the submittal of complete redesignation requests. September 4, 1992 Calcagni memorandum (''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division). See also: September 17, 1993 Shapiro memorandum (''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standard (NAAQS) on or after November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator, Air and Radiation Division); 60 FR 12459, 12465–12466 (March 7, 1995) (redesignation of Detroit-Ann Arbor); *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004), which upheld this interpretation; and, 68 FR 25418, 25424, 25427 (May 12, 2003) (redesignation of St. Louis). At the time the redesignation request for LaPorte County was submitted, the area was not classified under subpart 1 and no subpart 1 requirements were applicable for purposes of redesignation.

Second, it would be inequitable to retroactively apply any new SIP requirements that were not applicable at the time the complete redesignation request was submitted, but which might later become applicable. The D.C. Circuit has recognized the inequity of such retroactive rulemaking. See *Sierra Club* v. *Whitman,* 285 F.3d 63 (D.C. Cir. 2002), in which the D.C. Circuit upheld a District Court's ruling refusing to make retroactive an EPA determination of nonattainment that was past the statutory attainment deadline. Such a determination would have resulted in the imposition of additional requirements on the area. The Court stated: ''Although EPA failed to make the nonattainment determination within the statutory time frame, Sierra Club's proposed solution only makes the situation worse. Retroactive relief would likely impose large costs on the States, which would face fines and suits for not implementing air pollution plans in 1997, even though they were not on notice at the time.'' *Id.* at 68. Similarly, here it would be unfair to penalize the area by applying to it for purposes of redesignation additional requirements under subpart 1 that were not in effect at the time Indiana submitted its redesignation request, but that might apply in the future.

Because LaPorte County was designated as Unclassifiable/Attainment under the 1-hour ozone standard and was never designated nonattainment for the 1-hour ozone standard, there are no outstanding 1-hour nonattainment area requirements that LaPorte County would be required to meet. Thus, we find that the Court's ruling does not result in any additional 1-hour requirements for purposes of redesignation of LaPorte County.

III. What Are the Criteria for Redesignation to Attainment?

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA authorizes redesignation provided that: (1) The Administrator determines that the area has attained the applicable NAAQS; (2) the Administrator has fully approved an applicable state implementation plan for the area under section 110(k) of the CAA; (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable emission reductions resulting from implementation of the applicable SIP, Federal air pollution control regulations, and other permanent and enforceable emission reductions; (4) the Administrator has fully approved a maintenance plan for the area meeting the requirements of section 175A of the CAA; and, (5) the state containing the area has met all requirements applicable to the area under section 110 and part D of the CAA.

EPA provided guidance on redesignations in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990 on April 16, 1992 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). The two main policy guidelines affecting the review of ozone redesignation requests are the following: ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (September 4, 1992 Calcagni memorandum); and, ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995. For additional policy guidelines used in the review of ozone redesignation requests, see our proposed rule for the redesignation of the Evansville, Indiana ozone nonattainment area at 70 FR 53606 (September 9, 2005).

IV. What Are EPA's Analyses of the State's Requests and What Are the Bases for EPA's Proposed Action?

EPA is proposing to: (1) Determine that LaPorte County has attained the 8-hour ozone standard; (2) approve the ozone maintenance plan for this County and the VOC and NO_X MVEBs supported by this maintenance plan; and, (3) approve the redesignation of this County to attainment of the 8-hour ozone NAAQS. The bases for our proposed determination and approvals follow.

1. LaPorte County Has Attained the 8-Hour Ozone NAAQS

For ozone, an area may be considered to be attaining the 8-hour ozone NAAQS if there are no violations of the NAAQS, as determined in accordance with 40 CFR 50.10 and appendix I, based on the most recent three complete, consecutive calendar years of quality-assured air quality monitoring data at all ozone monitoring sites in the area and in its nearby downwind environs. To attain this standard, the average of the annual fourth-high daily maximum 8-hour average ozone concentrations measured and recorded at each monitor (the monitoring site's ozone design value) within the area and in its nearby downwind environs over the three-year period must not exceed the ozone standard. Based on an ozone data rounding convention described in 40 CFR part 50, appendix I, the 8-hour standard is attained if the area's ozone design value [3] is 0.084 ppm (84 ppb) or lower. The data must be collected and quality-assured in accordance with 40 CFR part 58, and must be recorded in EPA's Air Quality System (AQS). The ozone monitors generally should have remained at the same locations for the duration of the monitoring period required to demonstrate attainment (for three years or more). The data supporting attainment of the standard

[3] The worst-case monitoring site-specific ozone design value in the area or in its affected downwind environs.

must be complete in accordance with 40 CFR part 50, appendix I.

As part of the May 30, 2006 ozone redesignation request, IDEM submitted ozone monitoring data indicating the highest four daily maximum 8-hour ozone concentrations for each monitoring site in LaPorte County (the Michigan City and LaPorte ozone monitoring sites) for each year during the 2003–2005 period. These worst-case ozone concentrations are part of the quality-assured ozone data that have been entered into EPA's AQS. The annual fourth-high 8-hour daily maximum ozone concentrations, along with their three-year averages are summarized in Table 1.

TABLE 1.—FOURTH-HIGH 8-HOUR OZONE CONCENTRATIONS

[In parts per billion (ppb)]

County	Monitoring site	2003	2004	2005	Average
LaPorte	Michigan City	82	70	84	79
LaPorte	LaPorte	84	68	89	80

These data show that the average fourth-high daily maximum 8-hour ozone concentrations for the monitoring sites in LaPorte County are all below the 85 ppb ozone standard violation cut-off. The data support the conclusion that LaPorte County did not experience a monitored violation of the 8-hour ozone standard during the 2003–2005 period.

We also note that the 8-hour ozone NAAQS continued to be attained in LaPorte County through 2006. Data in the AQS show that, in 2006, the Michigan City monitor recorded a daily maximum fourth-high 8-hour ozone concentration of 75 ppb, and the LaPorte monitor recorded a daily maximum fourth-high 8-hour ozone concentration of 69 ppb.

The State has committed to continue ozone monitoring in this area during the maintenance period, through 2020. IDEM also commits to consult with the EPA prior to making any changes in the existing monitoring network.

During our review of the LaPorte ozone monitoring data contained in EPA's AQS, we noted that the annual percentages of reported daily maximum 8-hour ozone concentrations for the LaPorte monitoring site during the 2003–2005 ozone seasons (April through September in Indiana) were the following: 90 percent in 2003; 65 percent in 2004; and 74 percent in 2005. This is not consistent with the three-year 90 percent annual average completeness requirement and the 75 percent annual minimum completeness requirement of 40 CFR part 50, appendix I. It should be noted, however, that appendix I provides for the consideration of surrounding ozone monitoring data to support alternative conclusions regarding data completeness. More specifically, it provides that, when computing whether the minimum data completeness requirements have been met, meteorological and ambient data may be sufficient to demonstrate that meteorological conditions on missing data days were not conducive to peak ozone concentrations above the level of the standard. Missing days assumed to have peak ozone concentrations less than the standard are counted for purposes of meeting the data completeness requirements as having valid maximum 8-hour ozone concentrations.

On August 24, 2006, IDEM submitted supplemental data and documentation to support the conclusion that all days in 2003, 2004, and 2005 with missing ozone data were days in which the ozone standard was likely to not have been exceeded at the LaPorte site. We believe that IDEM's analysis supports an assumption of data completeness for the LaPorte monitoring site and, therefore, agree that the LaPorte ozone data for 2003–2005 meet the data completeness requirements. IDEM has appropriately flagged the ozone data in the AQS for this monitoring site supporting this conclusion.

The data submitted by the State demonstrate that LaPorte County has attained the 8-hour ozone NAAQS. Therefore, we propose to find that LaPorte County has attained the 8-hour ozone standard.

2. LaPorte County Has Met All Applicable Requirements Under Section 110 and Part D of the CAA and the Area Has a Fully Approved SIP Under Section 110(k) of the CAA

EPA has determined that Indiana has met all currently applicable SIP requirements for LaPorte County under section 110 of the CAA (general SIP requirements). EPA has also determined that the Indiana SIP meets currently applicable SIP requirements under part D of title I of the CAA (requirements specific to basic and subpart 2 ozone nonattainment areas). See section 107(d)(3)(E)(v) of the CAA. In addition, EPA has determined that the Indiana SIP is fully approved with respect to all applicable requirements. See section 107(d)(3)(E)(ii) of the CAA. In making these determinations, EPA ascertained what requirements are applicable to the area, and determined that the applicable portions of the SIP meeting these requirements are fully approved under section 110(k) of the CAA. We note that SIPs must be fully approved only with respect to currently applicable requirements of the CAA, those CAA requirements applicable to LaPorte County at the time the State submitted the final, complete ozone redesignation request for this area.

a. LaPorte County Has Met All Applicable Requirements Under Section 110 and Part D of the CAA

The September 4, 1992 Calcagni memorandum describes EPA's interpretation of section 107(D)(3)(E) of the CAA. Under this interpretation, to qualify for redesignation of an area to attainment, the State and the area must meet the relevant CAA requirements that come due prior to the State's submittal of a complete redesignation request for the area. See also a September 17, 1993 memorandum from Michael Shapiro, Acting Assistant Administrator for Air and Radiation, ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992'' and 66 FR 12459, 12465–12466 (March 7, 1995) (redesignation of Detroit-Ann Arbor, Michigan to attainment of the 1-hour ozone NAAQS). Applicable requirements of the CAA that come due subsequent to the State's submittal of a complete redesignation request remain applicable until a redesignation to attainment of the standard is approved, but are not required as a prerequisite to redesignation. See section 175A(c) of the CAA. *Sierra Club* v. *EPA*, 375 F.3d 537 (7th Cir. 2004). See also 68 FR 25424, 25427 (May 12, 2003) (redesignation of the St. Louis/East St. Louis area to attainment of the 1-hour ozone NAAQS).

General SIP requirements: Section 110(a) of title I of the CAA contains the general requirements for a SIP, which include: enforceable emission limitations and other control measures, means, or techniques; provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality; and programs to enforce the emission limitations. SIP elements and requirements are specified in section 110(a)(2) of title I, part A of the CAA. These requirements and SIP elements include, but are not limited to, the following: (a) Submittal of a SIP that has been adopted by the State after reasonable public notice and a hearing; (b) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (c) implementation of a source permit program; (d) provisions for the implementation of new source part C requirements (Prevention of Significant Deterioration (PSD)) and new source part D requirements (New Source Review (NSR)); (e) criteria for stationary source emission control measures, monitoring, and reporting; (f) provisions for air quality modeling; and, (g) provisions for public and local agency participation.

SIP requirements and elements are discussed in the following EPA documents: ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992; ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator, September 17, 1993. See also other guidance documents listed above.

Section 110(a)(2)(D) of the CAA requires SIPs to contain certain measures to prevent sources in one state from significantly contributing to air quality problems in another state. To implement this provision, EPA required states to establish programs to address transport of air pollutants (NO_X SIP call, Clean Air Interstate Rule (CAIR)). EPA has also found, generally, that states have not submitted SIPs under section 110(a)(1) of the CAA to meet the interstate transport requirements of section 110(a)(2)(D)(i) of the CAA (70 FR 21147, April 25, 2005). However, the section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's classification. EPA believes that the requirements linked with a particular nonattainment area's classification are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state.

We believe that these requirements should not be construed to be applicable requirements for purposes of redesignation. Further, we believe that the other section 110 elements described above that are not connected with nonattainment plan submissions and that are not linked with an area's attainment status are also not applicable requirements for purposes of redesignation. A state remains subject to these requirements after an area is redesignated to attainment. We conclude that only the section 110 and part D requirements which are linked with an area's designation and classification are the relevant measures in evaluating this aspect of a redesignation request. This approach is consistent with EPA's existing policy on applicability of conformity and oxygenated fuels requirements for redesignation purposes, as well as with section 184 ozone transport requirements. See: Reading, Pennsylvania proposed and final rulemakings (61 FR 53174–53176, October 10, 1996 and 62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida final rulemaking (60 FR 62748, December 7, 1995). See also the discussion on this issue in the Cincinnati, Ohio ozone redesignation (65 FR 37890, June 19, 2000), and the Pittsburgh, Pennsylvania ozone redesignation (66 FR 50399, October 19, 2001). In addition, Indiana's response to the CAIR rule was due in September 2006. Because this deadline had not yet passed when the State submitted the final, complete redesignation request, the State's CAIR submittal is also not an applicable requirement for redesignation purposes.

We believe that section 110 elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. Nonetheless, we also note that EPA has previously approved provisions in the Indiana SIP addressing section 110 elements under the 1-hour ozone standard. We have analyzed the Indiana SIP as codified in 40 CFR 52, subpart P, and have determined that it is consistent with the requirements of section 110(a)(2) of the CAA. The SIP, which has been adopted after reasonable public notice and hearing, contains enforceable emission limitations; requires monitoring, compiling, and analyzing ambient air quality data; requires preconstruction review of new major stationary sources and major modifications of existing sources; provides for adequate funding, staff, and associated resources necessary to implement its requirements; and, requires stationary source emissions monitoring and reporting, and otherwise satisfies the applicable requirements of section 110(a)(2).

Part D SIP requirements: EPA has determined that the Indiana SIP meets applicable SIP requirements under part D of the CAA. Under part D, an area's classification (marginal, moderate, serious, severe, and extreme) indicates the requirements to which it will be subject. Subpart 1 of part D, found in sections 172–176 of the CAA, sets forth the basic nonattainment area plan requirements applicable to all nonattainment areas. Subpart 2 of part D, found in section 182 of the CAA, establishes additional specific requirements depending on the area's nonattainment classification.

Part D, subpart 1 requirements: For purposes of evaluating this redesignation request, the applicable subpart 1 part D requirements for all nonattainment areas are contained in sections 172(c)(1)–(9) and 176. A thorough discussion of the requirements of section 172 can be found in the General Preamble for Implementation of Title I (57 FR 13498). (See also 68 FR 4852–4853 in a St. Louis ozone redesignation notice of proposed rulemaking for a discussion of section 172 requirements.)

As noted in a previous section of this proposed rule, no requirements under part D of the CAA came due for LaPorte County prior to the State's May 30, 2006 submittal of a complete redesignation request. For example, the requirement for an ozone attainment demonstration, as contained in section 172(c)(1), was not yet applicable, nor were the requirements for Reasonably Available Control Measures (RACM) and Reasonably Available Control Technology (RACT) (section 172(c)(1)), Reasonable Further Progress (RFP) (section 172(c)(2)), and attainment plan and RFP contingency measures (section 172(c)(9)). All of these SIP elements were required for submittal after May 30, 2006. Therefore, none of the part D requirements are applicable to LaPorte County for purposes of redesignation.

Section 176 conformity requirements: Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally-supported or funded activities, including highway projects, conform to the air planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects developed, funded, or approved under Title 23 U.S.C. and the Federal Transit Act (transportation conformity) as well as to all other federally-supported or funded projects (general conformity). State conformity SIP revisions must be consistent with Federal conformity regulations that the CAA required the EPA to promulgate.

In addition to the fact that part D requirements did not become due prior to Indiana's submission of the complete ozone redesignation request for LaPorte County, and, therefore, are not applicable for redesignation purposes, EPA similarly believes that it is reasonable to interpret the conformity requirements as not applying for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA. In addition, please note that it is reasonable to interpret the conformity requirements as not applying for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA because state conformity rules are still required after redesignation of an area to attainment of a NAAQS and Federal conformity rules apply where state rules have not been approved. See *Wall* v. *EPA*, 265 F.3d 426 (6th Cir. 2001). See also 60 FR 62748 (December 7, 1995) (Tampa, Florida).

Part D, subpart 2 requirements: Similar to the subpart 1 requirements, EPA believes that the subpart 2 requirements that apply to LaPorte County do not apply to a consideration of Indiana's ozone redesignation request because the State submitted a complete ozone redesignation request for LaPorte County before any of the applicable subpart 2 requirements became due.

The May 10, 1995 Seitz memorandum (see ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995) states that certain SIP revisions need not be submitted for EPA to approve a redesignation request since the requirements would no longer be considered applicable requirements as long as the area continues to attain the standard. As set forth in this policy, EPA believes it is reasonable to interpret the provisions regarding RFP and attainment demonstrations, along with certain other related provisions, as not requiring further state submissions to achieve attainment if an area is in fact attaining the standard. In the May 10, 1995 memorandum, EPA articulated in detail its interpretation that certain requirements of subparts 1 and 2 are not applicable once an area has attained the standard, for as long as it continues to do so.

The United States Court of Appeals for the Tenth Circuit has upheld this interpretation, *Sierra Club* v. *EPA*, 99 F.3d 1551 (10th Cir. 1996), as has the U.S. Court of Appeals for the Seventh Circuit. *Sierra Club* v. *EPA*, 375 F.3d 537 (7th Cir. 2004). In addition, EPA has explained in rulemaking actions on the 1-hour ozone standard its rationale for the reasonableness of this interpretation of the CAA. See: 67 FR 49600 (July 31, 2002); 65 FR 37879 (June 19, 2000); 65 FR 3630, 3631–32 (January 24, 2000) (Cincinnati-Hamilton, Ohio, Kentucky); 61 FR 20458 (May 7, 1996) (Cleveland-Akron-Lorain, Ohio); 66 FR 53094 (October 19, 2001) (Pittsburgh-Beaver Valley, Pennsylvania); 60 FR 37366 (July 20, 1995); 61 FR 31832–33 (June 21, 1996) (Grand Rapids, Michigan); 60 FR 36723 (July 18, 1995) (Salt Lake and Davis Counties, Utah); 68 FR 4847, 4848, 4851, 4855 (January 30, 2003); 68 FR 25418 (May 12, 2003) (St. Louis, Missouri); and, 66 FR 27484, 27486 (May 17, 2001) (Louisville, Kentucky).

EPA has also determined that areas being redesignated need not comply with the requirement that a New Source Review (NSR) program be approved prior to redesignation, provided that the area demonstrates maintenance of the standard without part D NSR, since Prevention of Significant Deterioration (PSD) requirements will apply after redesignation. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.'' Indiana has demonstrated that LaPorte County will be able to maintain the 8-hour ozone standard without part D NSR in effect, and, therefore, we conclude that the State need not have a fully approved part D NSR program prior to approval of the redesignation request. The State's PSD program will become effective in LaPorte County upon redesignation to attainment. See rulemakings for Detroit, Michigan (60 FR 12467–12468, March 7, 1995); Cleveland-Akron-Lorain, Ohio (61 FR 20458, 20469–20470, May 7, 1996); Louisville, Kentucky (66 FR 53665, October 23, 2001); Grand Rapids, Michigan (61 FR 31834–31837, June 21, 1996).

We conclude that the State and LaPorte County have satisfied all applicable requirements under section 110 and part D of the CAA to the extent that the requirements apply for the purposes of reviewing the State's ozone redesignation request.

b. LaPorte County Has a Fully Approved Applicable SIP Under Section 110(k) of the CAA

EPA has fully approved the Indiana SIP for LaPorte County under section 110(k) of the CAA for all applicable requirements. EPA may rely on prior SIP approvals in approving a redesignation request (See the September 4, 1992 John Calcagni memorandum, page 3, *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–990 (6th Cir. 1998), *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001)), plus any additional measures it may approve in conjunction with a redesignation action. See 68 FR 25426 (May 12, 2003). Since the passage of the CAA of 1970, Indiana has adopted and submitted, and EPA has fully approved, provisions addressing the various required SIP elements applicable to LaPorte County for purposes of redesignation. No LaPorte County SIP provisions are currently disapproved, conditionally approved, or partially approved. As indicated above, EPA believes that the section 110 elements not connected with nonattainment plan submissions and not linked to the area's nonattainment status are not applicable requirements for purposes of review of the State's redesignation request. EPA has concluded that the section 110 SIP submission approved under the 1-hour ozone standard will be adequate for purposes of attaining and maintaining the 8-hour standard. EPA also believes that since the part D requirements did not become due prior to Indiana's submission of a final, complete redesignation request, they also are not applicable requirements for purposes of redesignation.

3. The Air Quality Improvement in LaPorte County Is Due To Permanent and Enforceable Reductions in Emissions From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Emission Reductions

EPA believes that the State of Indiana has demonstrated that the observed air

quality improvement in LaPorte County is due to permanent and enforceable emission reductions resulting from implementation of the SIP, Federal measures, and other State-adopted measures.

The State has documented the changes in VOC and NO_X emissions from anthropogenic (man-made or man-based) sources in LaPorte County between 1996 and 2004 and the changes in NO_X emissions from Electric Generating Units (EGUs) in Northwest Indiana (Jasper, Lake, LaPorte, and Porter Counties) and statewide between 1999 and 2005. LaPorte County was monitored in violation of the 8-hour ozone NAAQS during the period of 1996 through 1999 and monitored in attainment with the NAAQS during the period of 2003 through 2005. The VOC and NO_X emissions for LaPorte County for various years during the period of 1996 through 2004 are given in Table 2.

TABLE 2.—VOC AND NO_X EMISSIONS TRENDS IN LAPORTE COUNTY FOR ANTHROPOGENIC SOURCES

[Emissions in tons/summer day]

Pollutant	1996	1999	2002	2004
VOC	31.0	29.7	24.5	24.0
NO_X	83.7	45.4	71.6	44.4

The NO_X emissions trends for EGUs in Northwest Indiana and statewide for Table 3. The NO_X emissions for LaPorte County and the EGU NO_X emissions from Northwest Indiana and statewide have shown significant downward trends from 1996 and 1999, 8-hour standard violation years, to 2004 and 2005, attainment years (and from 2002, a violation year, to 2004, an attainment year). IDEM notes that the NO_X emissions in Northwest Indiana and statewide declined significantly as a result of the implementation of the Indiana NO_X SIP (in response to EPA's NO_X SIP call) and acid rain control regulations, both of which led to permanent, enforceable emission reductions.

TABLE 3.—NO_X EMISSION TRENDS FOR ELECTRIC GENERATING UNITS IN NORTHWEST AND INDIANA STATEWIDE

[Emissions in thousands of tons per ozone season (April–September)]

Area	1999	2000	2001	2002	2003	2004	2005
Northwest Indiana	31.8	25.0	27.4	22.7	18.0	11.8	10.6
Statewide	149.8	133.9	136.1	114.0	99.3	66.6	55.5

As noted in Table 2, the total VOC emissions in LaPorte County also declined between 1996 and 2004. IDEM notes that this emissions decline has resulted despite an increase in point source VOC emissions in this County due to source growth. VOC emission control measures have been implemented in LaPorte County constraining the impacts of new source growth in this County. The State's VOC rules were adopted in the mid-1990s, and include the following VOC control rules: 326 Indiana Administrative Code (IAC) 8–1–6 (Best Available Control Technology (BACT) for non-specific sources); 326 IAC 8–2 (surface coating emission limitations); 326 IAC (organic solvent degreasing operations); 326 IAC 8–4 (petroleum sources, including storage, transport, and marketing sources and petroleum refining); 326 IAC 8–5 (miscellaneous sources); and 326 IAC 8–6 (organic solvent emission limitations). These VOC control rules have been implemented statewide. Compliance with these rules has resulted in a decrease in point source VOC emissions in LaPorte County, offsetting some source growth, as well as decreasing VOC emissions in the remainder of Northwest Indiana and statewide. The VOC emission reductions resulting from the implementation of the VOC emission control rules are permanent and enforceable.

Since LaPorte County was not previously designated as a 1-hour ozone nonattainment area, no ozone precursor emission controls were specifically targeted at this County. Therefore, statewide and Federal emission control requirements have provided the majority of the VOC and NO_X emission reductions in LaPorte County and in the surrounding area.

Besides the statewide VOC RACT rules and NO_X emission control requirements, other Federal emission reduction requirements have resulted in decreased ozone precursor emissions in the Northwest Indiana area and/or will produce future emission reductions that will support maintenance of the ozone standard in LaPorte County (see a more detailed discussion on maintenance of the 8-hour ozone standard in LaPorte County below). These emission reduction requirements include the following:

Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards. These emission control requirements result in lower emissions from new cars and light duty trucks, including sport utility vehicles. The Federal rules are being phased in between 2004 and 2009. The EPA has estimated that, by the end of the phase-in period, the following vehicle NO_X emission reductions will occur nation-wide: passenger cars (light duty vehicles) (77 percent); light duty trucks, minivans, and sports utility vehicles (86 percent; and larger sports utility vehicles, vans, and heavier trucks (69 to 95 percent). VOC emission reductions are also expected to range from 12 to 18 percent, depending on vehicle class, over the same period. Although some of these emission reductions have already occurred by the 2004 attainment year, most of these emission reductions will occur during the maintenance period for LaPorte County.

Heavy-Duty Diesel Engines. In July 2000, EPA issued a final rule to control the emissions from highway heavy duty diesel engines, including low-sulfur diesel fuel standards. These emission reductions are being phased in between 2004 and 2007. This rule is expected to result in a 40 percent decrease in NO_X emissions from heavy duty diesel vehicles.

Non-Road Diesel Rule. Issued in May 2004, this rule generally applies to new stationary diesel engines used in certain industries, including construction, agriculture, and mining. In addition to

affecting engine design, this rule includes requirements for cleaner fuels. It is expected to reduce NO_X emissions from these engines by up to 90 percent, and to significantly reduce particulate matter and sulfur emissions from these engines in addition to the NO_X emission reduction. This rule did not affect 2004 emissions from these sources, but will limit emissions from new engines beginning in 2008.

Indiana commits to maintain all existing emission control measures that affect LaPorte County after this area is redesignated to attainment of the 8-hour ozone NAAQS. All changes in existing rules affecting LaPorte County and new rules subsequently needed to provide for the maintenance of the 8-hour ozone NAAQS in LaPorte County will be submitted to the EPA for approval as SIP revisions.

4. LaPorte County Has a Fully Approvable Ozone Maintenance Plan Pursuant to Section 175A of the CAA

In conjunction with its request to redesignate LaPorte County to attainment of the ozone NAAQS, Indiana submitted a SIP revision request to provide for maintenance of the 8-hour ozone NAAQS in LaPorte County for at least 10 years after the redesignation of this area to attainment of the 8-hour ozone NAAQS.

a. What Is Required in an Ozone Maintenance Plan?

Section 175A of the CAA sets forth the required elements of air quality maintenance plans for areas seeking redesignation from nonattainment to attainment of a NAAQS. Under section 175A, a maintenance plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after the Administrator approves the redesignation to attainment. Eight years after the redesignation, the State must submit a revised maintenance plan which demonstrates maintenance of the standard for 10 years following the initial 10-year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary, to assure prompt correction of any future NAAQS violations. The September 4, 1992 John Calcagni memorandum provides additional guidance on the content of maintenance plans. An ozone maintenance plan should, at minimum, address the following items: (1) The attainment VOC and NO_X emissions inventories; (2) a maintenance demonstration showing maintenance for the 10 years of the maintenance period; (3) a commitment to maintain the existing monitoring network; (4) factors and procedures to be used for verification of continued attainment; and, (5) a contingency plan to prevent and/or correct a future violation of the NAAQS.

b. What Are the Attainment Emission Inventories for LaPorte County?

IDEM prepared comprehensive VOC and NO_X emission inventories for LaPorte County, including point (significant stationary sources), area (smaller and widely-distributed stationary sources), mobile on-road, and mobile non-road sources for 2004 (the base year/attainment year). To develop the attainment year emission inventories, IDEM used the following approaches and sources of data:

Area Sources—Area source VOC and NO_X emissions were projected from Indiana's 2002 periodic emissions inventory, which was previously submitted to the EPA.

Mobile On-Road Sources—Mobile source emissions were calculated using the MOBILE6 emission factor model and traffic data (vehicle miles traveled, vehicle speeds, and vehicle type and age distributions) extracted from the region's travel-demand model. IDEM has provided detailed data summaries to document the calculation of mobile on-road VOC and NO_X emissions for 2004, as well as for the projection years of 2010 and 2020 (further discussed below).

Point Source Emissions—2004 point source emissions were compiled using IDEM's 2004 annual emissions statement database and the 2005 EPA Air Markets acid rain emissions inventory database.

Mobile Non-Road Emissions—Non-road mobile source emissions were estimated by the EPA and documented in the 2002 National Emissions Inventory (NEI). IDEM used these emissions estimates along with growth factors to grow the non-road mobile source emissions to 2004. To address concerns about the accuracy of some of the emissions for various source categories in EPA's non-road emissions model, the Lake Michigan Air Directors Consortium (LADCO) contracted with several companies to review the base data used by the EPA and to make recommendations for corrections to the model. Emissions were estimated for commercial marine vessels and railroads. Recreational motorboat population and spatial surrogates (used to assign emissions to each county) were updated. The populations for the construction equipment category were reviewed and updated based on surveys completed in the Midwest, and the temporal allocation for agricultural sources was also updated. Based on these and other updates, the EPA provided a revised non-road estimation model, which was used for the 2004 projected non-road mobile source emissions.

The 2004 attainment year VOC and NO_X emissions for LaPorte County are summarized along with the 2010 and 2020 projected emissions for this County in Tables 4 and 5 below. They confirm that the State has acceptably derived and documented the attainment year VOC and NO_X emissions for LaPorte County.

c. Demonstration of Maintenance

As part of the May 30, 2006 redesignation request submittal, IDEM included a requested revision to the SIP to incorporate a 10-year ozone maintenance plan as required under section 175A of the CAA. The maintenance plan contains a maintenance demonstration. This demonstration shows maintenance of the 8-hour ozone NAAQS by documenting current and projected VOC and NO_X emissions and showing that future emissions of VOC and NO_X remain at or below the attainment year emission levels.[4] Note that a maintenance demonstration need not be based on modeling. See *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001), *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). See also 66 FR 53094, 53099–53100 (October 19, 2001) and 68 FR 25430–25432 (May 12, 2003).

Table 4 specifies the VOC emissions in LaPorte County for 2004, 2010, and 2020. IDEM chose 2020 as a projection year to meet the 10-year maintenance projection requirement, allowing several years for the State to complete its adoption of the ozone redesignation request and ozone maintenance plan and for the EPA to approve the redesignation request and maintenance plan. IDEM also chose 2010 as an interim year to demonstrate that VOC and NO_X emissions will remain below the attainment levels throughout the 10-year maintenance period.

Table 5, similar to Table 4, specifies the NO_X emissions in LaPorte County for 2004, 2010, and 2020. Together, Tables 4 and 5 demonstrate that LaPorte County should remain in attainment of the 8-hour ozone NAAQS between 2004 and 2020, for more than 10 years after EPA is expected to approve the

[4] The attainment year can be any of the three consecutive years in which the area has clean (below violation level) air quality data (2003, 2004, or 2005 for LaPorte County).

redesignation of LaPorte County to attainment of the 8-hour ozone NAAQS.

TABLE 4.—ATTAINMENT YEAR (2004) AND PROJECTED VOC EMISSIONS IN LAPORTE COUNTY

[Tons per summer day]

Source sector	Year		
	2004	2010	2020
Point	4.36	3.61	3.53
Area	7.17	7.51	8.14
On-Road Mobile	7.36	4.75	3.09
Off-Road Mobile	5.13	3.93	3.23
Total	24.02	19.80	17.99

TABLE 5.—ATTAINMENT YEAR AND PROJECTED NO_X EMISSIONS IN LAPORTE COUNTY

[Tons per summer day]

Source sector	Year		
	2004	2010	2020
Point	4.80	4.15	3.63
Area	1.13	1.20	1.26
On-Road Mobile	28.52	17.15	5.91
Off-road Mobile	9.96	7.57	6.41
Total	44.41	30.07	17.21

IDEM also notes that the State's EGU NO_X emission control rules stemming from EPA's NO_X SIP call, implemented beginning in 2004, and CAIR will further lower NO_X emissions in upwind areas, resulting in decreased ozone and ozone precursor transport into LaPorte County (the State did not project the emission decreases resulting from CAIR and did not document future NO_X emissions in upwind Counties). This will also support maintenance of the ozone standard in LaPorte County.

The emission projections for LaPorte County coupled with the expected impacts of the State's EGU NO_X rules and CAIR lead to the conclusion that LaPorte County should maintain the 8-hour ozone standard throughout the 10-year maintenance period. The decrease in local VOC and local and regional NO_X emissions indicate that peak ozone levels in LaPorte County may actually further decline during the 10-year ozone maintenance period.

IDEM has documented some of the procedures used to project emissions. On-road mobile sources were projected using the MOBILE6 emission factor model and projected traffic data obtained from the Northwest Indiana Regional Planning Commission (NIRPC), who maintains a travel demand forecast model that is capable of projecting changes in total daily Vehicle Miles Traveled (VMT). Emissions for the other major source sectors were determined using projected source activity/growth data provided by LADCO, as well as major source emissions data obtained periodically for all major sources statewide. IDEM's data demonstrate that emissions projections for LaPorte County are consistent with the planning analyses being conducted to attain the 8-hour ozone and fine particle (PM2.5) standards throughout Indiana and throughout the Lake Michigan area.

Based on the comparison of the projected emissions and the attainment year emissions, we conclude that IDEM has successfully demonstrated that the 8-hour ozone standard should be maintained in LaPorte County. We believe that this is especially likely given the expected impacts of the NO_X SIP call and CAIR. As noted by IDEM, this conclusion is further supported by the fact that other states in the eastern portion of the United States are expected to further reduce regional NO_X emissions through implementation of their own NO_X emission control rules for EGUs and other NO_X sources and through implementation of CAIR, reducing ozone and NO_X transport into LaPorte County.

d. Monitoring Network

IDEM commits to continue operating and maintaining an approved ozone monitoring network in LaPorte County in accordance with 40 CFR part 58 through the 10-year maintenance period. This will allow the confirmation of the maintenance of the 8-hour ozone standard in this area and the triggering of contingency measures if needed.

e. Verification of Continued Attainment

Continued attainment of the 8-hour ozone NAAQS in LaPorte County depends on the State's efforts toward tracking applicable indicators during the maintenance period. The State's plan for verifying continued attainment of the 8-hour ozone standard in LaPorte County consists, in part, of a plan to continue ambient ozone monitoring in accordance with the requirements of 40 CFR part 58. In addition, IDEM will periodically revise and review the VOC and NO_X emissions inventories for LaPorte County to assure that emissions growth is not threatening the continued attainment of the 8-hour ozone standard in this area. Revised emission inventories for this area will be prepared for 2005, 2008, and 2011 as necessary to comply with the emission inventory reporting requirements established in the CAA. The revised emissions will be compared with the 2004 attainment emissions and the 2020 projected maintenance year emissions to assure continued maintenance of the ozone standard.

f. Contingency Plan

The contingency plan provisions of the CAA are designed to result in prompt correction or prevention of violations of the NAAQS that might occur after redesignation of an area to

attainment of the NAAQS. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the State will promptly correct a violation of the NAAQS that might occur after redesignation. The maintenance plan must identify the contingency measures to be considered for possible adoption, a schedule and procedure for adoption and implementation of the selected contingency measures, and a time limit for action by the State. The State should also identify specific indicators to be used to determine when the contingency measures need to be adopted and implemented. The maintenance plan must include a requirement that the State will implement all measures with respect to control of the pollutant(s) that were controlled in the SIP before the redesignation of the area to attainment. See section 175A(d) of the CAA.

As required by section 175A of the CAA, Indiana has adopted a contingency plan to address a possible future ozone air quality problem. The contingency plan has two levels of actions/responses depending on whether a violation of the 8-hour ozone standard is only threatened (Warning Level Response) or has actually occurred (Action Level Response).

A Warning Level Response will be prompted whenever an annual (1-year) fourth-high monitored daily peak 8-hour ozone concentration of 89 ppb (or greater) occurs at any monitor in LaPorte County, or a 2-year averaged annual fourth-high daily peak 8-hour ozone concentration of 85 ppb or greater occurs at any monitor in LaPorte County. A Warning Level Response will consist of a study to determine whether the monitored ozone level indicates a trend toward higher ozone levels or whether emissions are increasing, threatening a future violation of the ozone NAAQS. The study will evaluate whether the trend, if any, is likely to continue, and, if so, emission control measures necessary to reverse the trend will be adopted, taking into consideration the ease and timing of implementation, as well as economic and social considerations. Implementation of necessary controls will take place as expeditiously as possible, but in no event later than 12 months from the conclusion of the most recent ozone season. If new emission controls are needed to reverse the adverse ozone trend, the procedures for emission control selection under the Action Level Response will be followed.

An Action Level Response will be triggered when a violation of the 8-hour ozone standard is monitored at any of the monitors in LaPorte County (when a 3-year average annual fourth-high monitored daily peak 8-hour ozone concentration of 85 ppb or higher is recorded at any monitor in LaPorte County). In this situation, IDEM will determine the additional emission control measures needed to assure future attainment of the 8-hour ozone NAAQS. IDEM will focus on emission control measures that can be implemented within 18 months from the close of the ozone season in which the ozone standard violation is monitored.

Adoption of any additional emission control measures prompted by either of the two response levels will be subject to the necessary administrative and legal processes dictated by State law. This process will include publication of public notices, providing the opportunity for a public hearing, and other measures required by Indiana law for rulemaking by State environmental boards. If a new emission control measure is already promulgated and scheduled for implementation at the Federal or State level, and that emission control measure is determined to be sufficient to address the air quality problem or adverse trend, additional local emission control measures may be determined to be unnecessary. IDEM will submit to the EPA an analysis to demonstrate that the proposed emission control measures or existing emission control measures are adequate to provide for future attainment of the 8-hour ozone NAAQS in LaPorte County.

Contingency measures contained in the maintenance plan are those emission controls or other measures that the State may choose to adopt and implement to correct existing or possible air quality problems in LaPorte County. These include, but are not limited to, the following:

i. Lower Reid vapor pressure gasoline requirements;

ii. Broader geographic applicability of existing emission control measures;

iii. Tightened RACT requirements on existing sources covered by EPA Control Technique Guidelines (CTGs) issued in response to the 1999 CAA amendments;

iv. Application of RACT to smaller existing sources;

v. Vehicle Inspection and Maintenance (I/M);

vi. One or more Transportation Control Measure (TCM) sufficient to achieve at least a 0.5 percent reduction in actual area-wide VOC emissions, to be selected from the following:

A. Trip reduction programs, including, but not limited to, employer-based transportation management plans, area-wide rideshare programs, work schedule programs, and telecommuting;

B. Transit improvement;

C. Traffic flow improvements; and,

D. Other new or innovative transportation measures not yet in widespread use that affect State and local governments as deemed appropriate;

vii. Alternative fuel and diesel retrofit programs for fleet vehicle operations;

viii. Controls on consumer products consistent with those adopted elsewhere in the United States;

ix. VOC or NO_X emission offsets for new or modified major sources;

x. VOC or NO_X emission offsets for new or modified minor sources;

xi. Increased ratio of emission offset required for new sources; and,

xii. VOC or NO_X emission controls on new minor sources (with VOC or NO_X emissions less than 100 tons per year).

g. Provisions for a Future Update of the Ozone Maintenance Plan

As required by section 175A(b) of the CAA, the State commits to submit to the EPA an update of the ozone maintenance plan eight years after redesignation of LaPorte County to attainment of the 8-hour ozone NAAQS. The updated maintenance plan will provide for maintenance of the 8-hour ozone standard in LaPorte County for an additional 10 years beyond the period covered by the initial ozone maintenance plan.

V. Has Indiana Adopted Acceptable Motor Vehicle Emissions Budgets for the End of the 10-Year Maintenance Plan Which Can Be Used To Support Conformity Determinations?

A. How Are the Motor Vehicle Emission Budgets Developed and What Are the Motor Vehicle Emission Budgets for LaPorte County?

Under the CAA, states are required to submit, at various times, SIP revisions and ozone maintenance plans for applicable areas (for ozone nonattainment areas and for areas seeking redesignations to attainment of the ozone standard or revising existing ozone maintenance plans). These emission control SIP revisions (e.g., reasonable further progress and attainment demonstration SIP revisions), including ozone maintenance plans, must create MVEBs based on on-road mobile source emissions allocated to highway and transit vehicle use that, together with emissions from other sources in the area, will provide for attainment or maintenance of the ozone NAAQS.

Under 40 CFR part 93, MVEBs for an area seeking a redesignation to

attainment of the NAAQS are established for the last year of the maintenance plan. The MVEBs serve as ceilings on emissions from an area's planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993 transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEBs in the SIP and how to revise the MVEBs if needed.

Under section 176(c) of the CAA, new transportation projects, such as the construction of new highways, must ''conform'' to (i.e., be consistent with) the part of the SIP that addresses emissions from cars and trucks. Conformity to the SIP means that transportation activities will not cause new air quality standard violations, or delay timely attainment of the NAAQS. If a transportation plan does not conform, most new transportation projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA's policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities to a SIP.

When reviewing SIP revisions containing MVEBs, including attainment strategies, rate-of-progress plans, and maintenance plans, EPA must affirmatively find that the MVEBs are ''adequate'' for use in determining transportation conformity. Once EPA affirmatively finds the submitted MVEBs to be adequate for transportation conformity purposes, the MVEBs are used by state and Federal agencies in determining whether proposed transportation projects conform to the SIPs as required by section 176(c) of the CAA. EPA's substantive criteria for determining the adequacy of MVEBs are specified in 40 CFR 93.118(e)(4).

EPA's process for determining adequacy of MVEBs consists of three basic steps: (1) Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEBs during a public comment period; and, (3) making a finding of adequacy. The process of determining the adequacy of submitted SIP MVEBs was initially outlined in EPA's May 14, 1999 guidance, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.'' This guidance was finalized in the Transportation Conformity Rule Amendments for the ''New 8-Hour Ozone and PM2.5 National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas: Transportation Conformity Rule Amendments—Response to Court Decision and Additional Rule Change'' published on July 1, 2004 (69 FR 40004). EPA follows this guidance and rulemaking in making its adequacy determinations.

The Transportation Conformity Rule, in 40 CFR 93.118(f), provides for MVEB adequacy findings through two mechanisms. First, section 93.118(f)(1) provides for posting a notice to the EPA conformity Web site at: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm* and providing a 30-day public comment period. Second, a mechanism is described in 40 CFR 93.118(f)(2) which provides that EPA can review the adequacy of an implementation plan MVEB simultaneously with its review of the implementation plan itself.

The LaPorte County 10-year maintenance plan contains VOC and NO_X MVEBs for 2020. EPA has reviewed the submittal and the proposed VOC and NO_X MVEBs for LaPorte County and finds that the MVEBs meet the adequacy criteria in the Transportation Conformity Rule. Any and all comments on the approvability of the MVEBs should be submitted during the comment period stated in the **DATES** section of this notice.

EPA, through this rulemaking, is proposing to approve the MVEBs for use to determine transportation conformity in LaPorte County because EPA has determined that the budgets are consistent with the control measures in the SIP and that LaPorte County can maintain attainment of the 8-hour ozone NAAQS for the relevant required 10-year period with mobile source emissions at the levels of the MVEBs. IDEM has determined the 2020 MVEBs for LaPorte County to be 3.40 tons per day for VOC and 6.50 tons per day for NO_X. It should be noted that these MVEBs exceed the on-road mobile source VOC and NO_X emissions projected by IDEM for 2020, as summarized in Tables 4 and 5 above (''On-Road Mobile'' source sector). Through discussions with all organizations involved in transportation planning for LaPorte County, IDEM decided to include safety margins of 0.31 tons per day for VOC and 0.59 tons per day for NO_X in the MVEBs to provide for mobile source growth not anticipated in the projected 2020 emissions. Indiana has demonstrated that LaPorte County can maintain the 8-hour ozone NAAQS with mobile source emissions of 3.40 tons per day of VOC and 6.50 tons per day of NO_X in 2020 since total source emissions with the increased mobile source emissions will remain under the attainment year levels.

B. What Is a Safety Margin?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. As noted in Tables 4 and 5, LaPorte County emissions are projected to have safety margins of 7.03 tons per day for VOC and 37.20 tons per day for NO_X in 2020, the difference between the 2004, attainment year, and 2020 VOC and NO_X emissions for all sources in LaPorte County.

The MVEBs requested by IDEM contain mobile source safety margins (selected by the State) significantly smaller than the safety margins reflected in the total emissions for LaPorte County. The State is not requesting allocation of the entire available safety margins actually reflected in the demonstration of maintenance (in Tables 4 and 5). Therefore, even though the State is requesting MVEBs that exceed the on-road mobile source emissions for 2020 contained in the demonstration of maintenance, the increase in on-road mobile source emissions that can be considered for transportation conformity purposes is well within the safety margins of the ozone maintenance demonstration.

C. Are the MVEBs Approvable?

The VOC and NO_X MVEBs for LaPorte County are approvable because they maintain the total emissions for LaPorte County at or below the attainment year emission inventory levels, as required by the transportation conformity regulations.

VI. What Is the Effect of EPA's Proposed Action?

Approval of the redesignation request would change the official designation of LaPorte County for the 8-hour ozone NAAQS, found at 40 CFR part 81, from nonattainment to attainment. It would also incorporate into the Indiana SIP a plan for maintaining the ozone NAAQS through 2020. The maintenance plan includes contingency measures to remedy possible future violations of the 8-hour ozone NAAQS, and establishes MVEBs of 3.40 tons per day for VOC and 6.50 tons per day for NO_X.

VII. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, September 30, 1993), this action is not a ''significant regulatory action'' and, therefore, is not subject to review

by the Office of Management and Budget.

Paperwork Reduction Act

This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Regulatory Flexibility Act

This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Unfunded Mandates Reform Act

Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant regulatory action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272, requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impractical. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Clean Air Act. Therefore, the requirements of section 12(d) of the NTTAA do not apply.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

40 CFR Part 81

Air pollution control, Environmental protection, National parks, Wilderness areas.

Dated: April 6, 2007.

Walter W. Kovalick,

Acting Regional Administrator, Region 5.

[FR Doc. E7–7348 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2006–1022; FRL–8301–7]

Redesignation of the Ohio Portion of the Youngstown Area to Attainment of the 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On February 15, 2007, the Ohio Environmental Protection Agency (Ohio EPA), submitted a request for a redesignation of its portion of the Youngstown area to attainment of the 8-hour ozone National Ambient Air Quality Standard (NAAQS), and a request for EPA approval of an ozone maintenance plan for Mahoning, Trumbull, and Columbiana Counties, Ohio. The State public hearing on the submittal was held on January 9, 2007.

EPA is proposing to determine that the Youngstown area has attained the 8-hour ozone NAAQS. EPA believes that the State's ozone maintenance plan for the area is acceptable and, in conjunction with projected emissions in the Pennsylvania portion of the area (Mercer County), will provide for maintenance of the 8-hour ozone NAAQS in these Counties through 2018. EPA is proposing approval of the State's request to redesignate Mahoning, Trumbull, and Columbiana Counties, Ohio to attainment of the 8-hour ozone NAAQS. EPA is also proposing to approve the Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Motor Vehicle Emission Budgets (MVEBs) for Mahoning, Trumbull, and Columbiana Counties, Ohio for purposes of transportation conformity determinations.

DATES: Comments must be received on or before May 18, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–1022, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: mooney.john@epa.gov.*
- *Fax:* (312) 886–5824.
- *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
- *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77

West Jackson Boulevard, Chicago, Illinois. Such deliveries are only accepted during the Regional Office's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office's official hours of operation are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2006–1022. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and should be free of any defects or viruses. For additional instructions on submitting comments, go to section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hardcopy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hardcopy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Patricia Morris, Environmental Scientist, at (312) 353–8656, before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Patricia Morris, Environmental Scientist, Criteria Pollutant Section, Air Programs Branch (AR–18), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8656, *morris.patricia@epa.gov*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' Is used, we mean the EPA. This supplementary information section is arranged as follows:

I. What Should I Consider as I Prepare My Comments for EPA?
II. What Action Is EPA Proposing To Take?
III. What Is the Background for These Actions?
IV. What Are the Criteria for Redesignation to Attainment?
V. What Is EPA's Analysis of the State's Request and What Is the Basis for EPA's Proposed Actions?
VI. Has Ohio Adopted Acceptable Motor Vehicle Emissions Budgets for the Ozone Maintenance Plan Which Can Be Used To Support Conformity Determinations?
VII. What Action Is EPA Taking?
VIII. Statutory and Executive Order Reviews

I. What Should I Consider as I Prepare My Comments for EPA?

When submitting comments, remember to:

1. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
2. Follow directions—The EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
4. Describe any assumptions and provide any technical information and/or data that you used.
5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
6. Provide specific examples to illustrate your concerns, and suggest alternatives.
7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
8. Make sure to submit your comments by the comment period deadline identified.

II. What Action Is EPA Proposing To Take?

We are proposing to take several related actions for Mahoning, Trumbull, and Columbiana Counties, Ohio. First, we are proposing to determine that the interstate Youngstown area (officially, the Youngstown-Warren-Sharon PA-OH area as defined for 8-hour ozone designation purposes) has attained the 8-hour ozone NAAQS. Second, we are proposing to approve Ohio's ozone maintenance plan for Mahoning, Trumbull, and Columbiana Counties as a requested revision to the Ohio State Implementation Plan (SIP). The maintenance plan is designed to keep the area in attainment of the 8-hour ozone NAAQS for the next 11 years, through 2018. Thirdly, we are proposing to find that the Ohio portion of this area (Mahoning, Trumbull, and Columbiana Counties), has met the requirements for redesignation to attainment of the 8-hour ozone NAAQS under section 107(d)(3)(E) of the Clean Air Act (CAA). Fourth, as supported by, and consistent with, the ozone maintenance plan, we are also proposing to approve the 2009 and 2018 VOC and NO_X MVEBs for Mahoning, Trumbull, and Columbiana Counties for transportation conformity determination purposes.

These proposed actions pertain to the designations of Mahoning, Trumbull, and Columbiana Counties, Ohio for the 8-hour ozone NAAQS and to the emission controls in these counties related to the attainment and maintenance of the 8-hour ozone NAAQS. If you own or operate a VOC or NO_X emissions source in these counties or live in these counties, this proposed rule may impact or apply to you. It may also impact you if you are involved in transportation planning or implementation of emission controls in this area. It may also impact you if you breathe air which has passed through the Youngstown area, or if you are concerned with clean air, human health or the environment.

III. What Is the Background for These Actions?

A. General Background

In EPA's April 30, 2004, rulemaking establishing designations and classifications for the 8-hour ozone standard, EPA designated the Youngstown area as subpart 1 nonattainment for the 8-hour ozone standard. EPA based the designation on ozone data collected during the 2001–2003 period.

On December 4, 2006, the State of Ohio submitted a request for redesignation of Mahoning, Trumbull,

and Columbiana Counties to attainment of the 8-hour ozone NAAQS based on ozone data collected in these counties and Mercer County, Pennsylvania during the 2004–2006 period. On January 9, 2007, the State of Ohio held a public hearing on the ozone redesignation request and ozone maintenance plan. Based on a February 15, 2007, submittal from the State, all information contained in the State's December 4, 2006, ozone redesignation request submittal was unchanged through the State's public review process.

B. What Is the Impact of the December 22, 2006, United States Court of Appeals Decision Regarding EPA's Phase 1 Implementation Rule?

1. Summary of Court Decision

On December 22, 2006, the U.S. Court of Appeals for the District of Columbia Circuit vacated EPA's Phase 1 Implementation Rule for the 8-hour Ozone Standard (69 FR 23951, April 30, 2004). *South Coast Air Quality Management Dist.* v. *EPA*, 472 F. 3d 882 (D.C. Cir. 2006). The Court held that certain provisions of EPA's Phase I Rule were inconsistent with the requirements of the Clean Air Act. The Court rejected EPA's reasons for implementing the 8-hour standard in nonattainment areas under Subpart 1 in lieu of subpart 2 of Title I, part D of the Act. The Court also held that EPA improperly failed to retain four measures required for 1-hour nonattainment areas under the anti-backsliding provisions of the regulations: (1) Nonattainment area New Source Review (NSR) requirements based on an area's 1-hour nonattainment classification; (2) Section 185 penalty fees for 1-hour severe or extreme nonattainment areas; (3) measures to be implemented pursuant to section 172(c)(9) or 182(c)(9) of the Act, on the contingency of an area not making reasonable further progress toward attainment of the 1-hour NAAQS, or for failure to attain that NAAQS; and (4) certain conformity requirements for certain types of Federal actions. The Court upheld EPA's authority to revoke the 1-hour standard provided there were adequate anti-backsliding provisions.

This section sets forth EPA's views on the potential effect of the Court's ruling on this redesignation action. For the reasons set forth below, EPA does not believe that the Court's ruling alters any requirements relevant to this redesignation action so as to preclude redesignation, and does not prevent EPA from finalizing this redesignation. EPA believes that the Court's decision, as it currently stands or as it may be modified based upon any petition for rehearing that has been filed, imposes no impediment to moving forward with redesignation of this area to attainment, because in either circumstance redesignation is appropriate under the relevant redesignation provisions of the Act and longstanding policies regarding redesignation requests.

2. Requirements Under the 8-Hour Standard

With respect to the 8-hour standard, the court's ruling rejected EPA's reasons for classifying areas under Subpart 1 for the 8-hour standard, and remanded that matter to the Agency. Consequently, it is possible that this area could, during a remand to EPA, be reclassified under Subpart 2. although any future decision by EPA to classify this area under subpart 2 might trigger additional future requirements for the area, EPA believes that this does not mean that redesignation cannot now go forward. This belief is based upon (1) EPA's longstanding policy of evaluating redesignation requirements in accordance with the requirements due at the time the request was submitted; and (2) consideration of the inequity of applying retroactively any requirements that might be applied in the future.

First, at the time the redesignation request was submitted, the Youngstown area was classified under Subpart 1 and was obligated to meet the Subpart 1 requirements. Under EPA's longstanding interpretation of section 107(d)(3)(E) of the Clean Air Act, to qualify for redesignation, states requesting redesignation to attainment must meet only the relevant SIP requirements that came due prior to the submittal of a complete redesignation request. September 4, 1992 Calcagni memorandum (''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division). See also Michael Shapiro Memorandum, September 17, 1993, and 60 FR 12459, 12465–66 (March 7, 1995) (redesignation of Detroit-Ann Arbor); *Sierra Club* v. *EPA*, 375 F. 3d 537 (7th Cir. 2004), which upheld this interpretation. See, *e.g.,* also 68 FR 25418, 25424, 25427 (May 12, 2003) (redesignation of St. Louis).

Moreover, it would be inequitable to retroactively apply any new SIP requirements that were not applicable at the time the request was submitted. The DC Circuit has recognized the inequity in such retroactive rulemaking. See *Sierra Club* v. *Whitman*, 285 F. 3d 63 (D.C. Cir. 2002), in which the DC Circuit upheld a District Court's ruling refusing to make retroactive an EPA determination of nonattainment that was past the statutory due date. Such a determination would have resulted in the imposition of additional requirements on the area. The Court stated: ''Although EPA failed to make the nonattainment determination within the statutory time frame, Sierra Club's proposed solution only makes the situation worse. Retroactive relief would likely impose large costs on the States, which would face fines and suits for not implementing air pollution prevention plans in 1997, even though they were not on notice at the time.'' *Id.* at 68. Similarly, here it would be unfair to penalize the area by applying to it for purposes of redesignation additional SIP requirements under Subpart 2 that were not in effect at the time it submitted its redesignation request.

3. Requirements Under the 1-Hour Standard

With respect to the 1-hour standard requirements, Mahoning and Trumbull Counties and also, separately, Columbiana County were designated as an Attainment area subject to a Clean Air Act section 175A maintenance plan under the 1-hour standard. The Court's ruling does not impact redesignation requests for these types of areas.

First, there are no conformity requirements that are relevant for redesignation requests, including the requirement to submit a transportation conformity SIP.[1] Under longstanding EPA policy, EPA believes that it is reasonable to interpret the conformity SIP requirement as not applying for purposes of evaluating a redesignation request under section 107(d) because state conformity rules are still required after redesignation and Federal conformity rules apply where state rules have not been approved. 40 CFR 51.390. See *Wall* v. *EPA*, 265 F. 3d 426 (6th Cir. 2001), upholding this interpretation. See also 60 FR 62748 (Dec. 7, 1995) (Tampa, FL redesignation). EPA approved Ohio's general and transportation conformity SIPs on March 11, 1996 (61 FR 9646) and May 30, 2000 (65 FR 34395), respectively.

Second, with respect to the three other anti-backsliding provisions for the 1-hour standard that the Court found were not properly retained, Mahoning and Trumbull Counties and separately

[1] Clean Air Act section 176(c)(4)(E) currently requires States to submit revisions to their SIPs to reflect certain Federal criteria and procedures for determining transportation conformity. Transportation conformity SIPs are different from the motor vehicle emissions budgets that are established in control strategy SIPs and maintenance plans.

Columbiana County are attainment areas subject to maintenance plans for the 1-hour standard, and the NSR, contingency measure (pursuant to section 172(c)(9) or 182(c)(9)) and fee provision requirements no longer apply to an area that has been redesignated to attainment of the 1-hour standard.

Thus the decision in *South Coast* should not alter requirements that would preclude EPA from finalizing the redesignation of this area.

IV. What Are the Criteria for Redesignation to Attainment?

Section 107(d)(3)(E) of the CAA allows for redesignation from nonattainment to attainment provided that:

(1) The Administrator determines that the area has attained the applicable NAAQS based on current air quality data; (2) the Administrator has fully approved an applicable state implementation plan for the area under section 110(k) of the CAA; (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable emission reductions resulting from implementation of the applicable SIP, Federal air pollution control regulations, and other permanent and enforceable emission reductions; (4) the Administrator has fully approved a maintenance plan for the area meeting the requirements of section 175A of the CAA; and (5) the state containing the area has met all requirements applicable to the area under section 110 and part D of the CAA.

EPA provided guidance on redesignations in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990 on April 16, 1992 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). EPA provided further guidance on processing redesignation requests in several guidance documents. A listing of pertinent guidance documents is provided in other redesignation actions (for example in the **Federal Register** of September 9, 2005, at 70 FR 53606).

V. What Is EPA's Analysis of the State's Request and What Is the Basis for EPA's Proposed Actions?

EPA is proposing to: (1) Determine that the Youngstown area has attained the 8-hour ozone standard; (2) approve the ozone maintenance plan for the Ohio portion of this area (Columbiana, Mahoning and Trumbull counties) and the VOC and NO_X MVEBs supported by this ozone maintenance plan; and, 3) approve the redesignation of the Ohio portion to attainment of the 8-hour ozone NAAQS.

The basis for our proposed determination and approval is as follows:

1. The Youngstown Area Has Attained the 8-Hour Ozone NAAQS

For ozone, an area may be considered to be attaining the 8-hour ozone NAAQS if there are no violations of the NAAQS, as determined in accordance with 40 CFR 50.10 and 40 CFR part 50 appendix I based on the most recent three complete, consecutive calendar years of quality-assured air quality monitoring data at all monitoring sites in the area. For each monitor in the area and nearby, the average of the annual fourth-high daily maximum 8-hour average ozone concentrations measured and recorded over a three-year period must not exceed the ozone standard. Based on the ozone data rounding convention described in 40 CFR part 50 appendix I, the 8-hour standard is attained if the area's ozone design value [2] is 0.085 ppm (85 ppb) or lower. The data must be collected and quality-assured in accordance with 40 CFR part 50, and must be recorded in EPA's Air Quality System (AQS). The ozone monitors generally should have remained at the same locations for the duration of the monitoring period required to demonstrate attainment (for three years or more [3]).

As part of the December 4, 2006, ozone redesignation request, the Ohio EPA submitted summarized ozone monitoring data indicating the top four daily maximum 8-hour ozone concentrations for each monitoring site in the Youngstown area during the 2004–2006 period. When the redesignation request was submitted, the complete 2006 monitoring data had not been quality assured and the data table submitted by Ohio EPA shows less than 75% data for the Ohio monitoring sites. However, now the Ohio EPA has completed all quality assurance procedures and the AQS system has over 75% data completeness for the Ohio sites. The following table summarizes the worst-case ozone concentrations that are part of the quality-assured ozone data collected and recorded in these Counties. These data have been entered into EPA's AQS. The annual fourth-high 8-hour daily maximum ozone concentrations, along with their three-year averages are summarized in Table 1.

TABLE 1.—FOURTH-HIGH 8-HOUR OZONE CONCENTRATIONS

[In parts per billion (ppb)]

County	Monitoring site	2004	2005	2006	Average
Mahoning OH	345 Oakhill	74	83	76	77
Trumbull OH	6346 Kinsman-Bloomfield Rd	78	83	74	78
Trumbull OH	842 Youngstown-Kingsville Rd	80	87	82	83
Mercer PA	Pa518 (New Castle Road) & Pa418	76	87	79	79

These data show that the site-specific ozone design values (average fourth-high daily maximum 8-hour ozone concentrations over the period of 2004–2006) for all monitoring sites in the Youngstown area are below the 85 ppb average ozone standard violation cut-off. These data support the conclusion that the Youngstown area ozone monitors did not record a violation of the 8-hour ozone standard during the 2004–2006 period, and monitored attainment of the standard during this period.

As discussed below with respect to the ozone maintenance plan, the State commits to continue ozone monitoring in these Counties.

We believe that the data submitted by the State to the AQS provide an adequate demonstration that the Youngstown area has attained the 8-hour ozone NAAQS. Therefore, we propose to find that the Youngstown

[2] The worst-case monitoring site-specific ozone design value in the area.

[3] EPA generally opposes terminating or relocating monitors at sites that are currently recording violations of the ozone standard. In addition, EPA encourages states to continue monitoring at most sites over the long term to confirm maintenance of the ozone standard and to support the determination of robust ozone concentration trends.

area, including Mahoning, Trumbull, and Columbiana Counties, Ohio, has attained the 8-hour ozone NAAQS.

2. Mahoning, Trumbull, and Columbiana Counties Have Met All Applicable Requirements Under Section 110 and Part D of the CAA and These Areas Have a Fully Approved SIP Under Section 110(k) of the CAA

We have determined that the State of Ohio has met all currently applicable SIP requirements for Mahoning, Trumbull, and Columbiana Counties under section 110 of the CAA (general SIP requirements). We have determined that the Ohio SIP meets currently applicable SIP requirements under subpart 1 part D of title I of the CAA (requirements specific to basic ozone nonattainment areas). See section 107(d)(3)(E)(v) of the CAA. In addition, we have determined that the Ohio SIP is fully approved with respect to all applicable requirements. See section 107(d)(3)(E)(ii) of the CAA. In making these determinations, we noted the CAA requirements that are applicable to the areas, and determined that the applicable portions of the SIP meeting these requirements are fully approved under section 110(k) of the CAA. We note that SIPs must be fully approved only with respect to currently applicable requirements of the CAA, those CAA requirements applicable to Mahoning, Trumbull, and Columbiana Counties at the time the State submits the final, complete ozone redesignation request for these areas.

a. Mahoning, Trumbull, and Columbiana Counties Have Met All Applicable Requirements Under Section 110 and Part D of the CAA

The September 4, 1992, Calcagni memorandum (see ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992) describes EPA's interpretation of section 107(d)(3)(E) of the CAA. To qualify for redesignation of an area to attainment under this interpretation, the state and the area must meet the relevant CAA requirements that come due prior to the State's submittal of a complete redesignation request for the area. See also the September 17, 1993, Michael Shapiro memorandum and 66 FR 12459, 12465–12466 (March 7, 1995) (redesignation of Detroit-Ann Arbor, Michigan to attainment of the 1-hour ozone NAAQS). Applicable requirements of the CAA that come due subsequent to the state's submittal of a complete redesignation request remain applicable until a redesignation of the area to attainment of the standard is approved, but are not required as prerequisites to redesignation. See Section 175A(c) of the CAA. *Sierra Club* v. *EPA*, 375 F.3d 537 (7th Cir. 2004). See also 68 FR 25424, 25427 (May 12, 2003) (redesignation of the St. Louis/East St. Louis area to attainment of the 1-hour ozone NAAQS).

General SIP requirements: Section 110(a) of title I of the CAA contains the general requirements for a SIP, which include: Enforceable emission limitations and other control measures, means, or techniques; provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality; and programs to enforce the emission limitations. General SIP elements and requirements are delineated in section 110(a)(2) of title I, part A of the CAA. These requirements and SIP elements include, but are not limited to, the following: (a) Submittal of a SIP that has been adopted by the State after reasonable public notice and a hearing; (b) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (c) implementation of a source permit program; (d) provisions for the implementation of part C requirements (Prevention of Significant Deterioration (PSD)) and part D requirements (New Source Review (NSR)) for new sources or major source modifications; (e) criteria for stationary source emission control measures, monitoring, and reporting; (f) provisions for air quality modeling; and, (g) provisions for public and local agency participation.

SIP requirements and elements are discussed in the following EPA documents: ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992; ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and ''State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator, September 17, 1993.

Section 110(a)(2)(D) of the CAA requires SIPs to contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA required states to establish programs to address transport of air pollutants (NO_X SIP call and Clean Air Interstate Rule (CAIR)). EPA has also found, generally, that states have not submitted SIPs under section 110(a)(1) of the CAA to meet the interstate transport requirements of section 110(a)(2)(D)(i) of the CAA (70 FR 21147, April 25, 2005). However, the section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's classification. EPA believes that the requirements linked with a particular nonattainment area's classification are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state.

We believe that these requirements should not be construed to be applicable requirements for purposes of redesignation. Further, we believe that the other section 110 elements described above that are not connected with nonattainment plan submissions and that are not linked with an area's attainment status are also not applicable requirements for purposes of redesignation. A state remains subject to these requirements after an area is redesignated to attainment. We conclude that only the section 110 and part D requirements which are linked with an area's designation and classification are the relevant measures for evaluating this aspect of a redesignation request. This approach is consistent with EPA's existing policy on applicability of conformity and oxygenated fuels requirements for redesignation purposes, as well as with section 184 ozone transport requirements. *See:* Reading, Pennsylvania proposed and final rulemakings (61 FR 53174–53176, October 10, 1996 and 62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida final rulemaking (60 FR 62748, December 7, 1995). See also the discussion on this issue in the Cincinnati, Ohio ozone redesignation (65 FR 37890, June 19, 2000), and the Pittsburgh, Pennsylvania ozone redesignation (66 FR 50399, October 19, 2001).

We believe that section 110 elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. Nonetheless, we also note that EPA has previously approved provisions in the Ohio SIP addressing section 110 elements under the 1-hour

ozone standard. We have analyzed the Ohio SIP as codified in 40 CFR part 52, subpart KK and have determined that it is consistent with the requirements of section 110(a)(2) of the CAA. The SIP, which has been adopted after reasonable public notice and hearing, contains enforceable emission limitations; requires monitoring, compiling, and analyzing ambient air quality data; requires preconstruction review of new major stationary sources and major modifications of existing sources; provisions for adequate funding, staff, and associated resources necessary to implement its requirements; requires stationary source emissions monitoring and reporting; and, otherwise satisfies the applicable requirements of section 110(a)(2).

Part D SIP requirements: EPA has determined that the Ohio SIP meets applicable ozone SIP requirements under part D of the CAA. Under part D, for ozone, an area's classification (subpart 1, marginal, moderate, serious, severe, and extreme) indicates the requirements to which it will be subject. Subpart 1 of part D, found in sections 172–176 of the CAA, sets forth the basic nonattainment area plan requirements applicable to all nonattainment areas. Subpart 2 of part D, found in section 182 of the CAA, establishes additional specific requirements for ozone nonattainment areas depending on the area's nonattainment classification.

Part D, subpart 1 requirements: For purposes of evaluating this redesignation request, the applicable requirements are those contained in Subpart I of Part D, in particular in sections 172(c)(1)–(9) and 176. A thorough discussion of the requirements of section 172 can be found in the General Preamble for Implementation of Title I (57 FR 13498). See also 68 FR 4852–4853, in an ozone redesignation notice of proposed rulemaking for the St. Louis area, for a discussion of section 172 requirements.

No requirements for the 8-hour ozone standard under part D of the CAA will come due for Mahoning, Trumbull, and Columbiana Counties prior to June 15, 2007. For example, the requirement for an ozone attainment demonstration, as contained in section 172(c)(1), is not yet applicable, nor are the requirements for Reasonably Available Control Measures (RACM) and Reasonably Available Control Technology (RACT) (section 172(c)(1)), Reasonable Further Progress (RFP) (section 172(c)(2)), and attainment plan and RFP contingency measures (section 172(c)(9)). All of these required SIP elements are required for submittal after June 15, 2007, and Ohio has submitted the public hearing transcript and response to comment to complete the ozone redesignation request and maintenance plan for Mahoning, Trumbull, and Columbiana Counties prior to the due date. Therefore, none of the part D requirements are considered to be applicable to Mahoning, Trumbull, and Columbiana Counties for purposes of redesignation for ozone.

Section 176 conformity requirements: Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally-supported or funded activities, including highway projects, conform to the air planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects developed, funded, or approved under Title 23 U.S.C. and the Federal Transit Act (transportation conformity) as well as to all other Federally-supported or funded projects (general conformity). State conformity SIP revisions must be consistent with Federal conformity regulations that the CAA required the EPA to promulgate.

In addition to the fact that part D requirements will not become due prior to Ohio's submittal of the complete ozone redesignation request for Mahoning, Trumbull, and Columbiana Counties, and, therefore, are not believed by the EPA to be applicable for redesignation purposes in this case, EPA similarly believes that it is reasonable to interpret the conformity requirements as not applying for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA. EPA believes that it is reasonable to interpret the conformity requirements as not applying for purposes of evaluating the ozone redesignation request under section 107(d) of the CAA because state conformity rules are still required after redesignation of areas to attainment of a NAAQS and Federal conformity rules apply where state rules have not been approved. See *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001). See also 60 FR 62748 (December 7, 1995) (Tampa, Florida). EPA approved Ohio's general and transportation conformity SIPs on March 11, 1996 (61 FR 9646) and May 30, 2000 (65 FR 34395), respectively.

We conclude that Mahoning, Trumbull, and Columbiana Counties have satisfied all applicable requirements under section 110 and part D of the CAA to the extent that these requirements apply for purposes of reviewing the State's ozone redesignation request.

b. Mahoning, Trumbull, and Columbiana Counties have a fully approved applicable SIP under section 110(k) of the CAA

EPA has fully approved the Ohio SIP for Mahoning, Trumbull, and Columbiana Counties under section 110(k) of the CAA for all applicable requirements. EPA may rely on prior SIP approvals in approving a redesignation request, plus any additional measures it may approve in conjunction with a redesignation action. See the September 4, 1992 John Calcagni memorandum, page 3, *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–990 (6th Cir. 1998), *Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001) 68 FR 25426 (May 12, 2003). Since the passage of the CAA of 1970, Ohio has adopted and submitted, and EPA has fully approved, provisions addressing the various required SIP elements applicable to Mahoning, Trumbull, and Columbiana Counties for purposes of redesignation. No Mahoning, Trumbull, or Columbiana County SIP provisions are currently disapproved, conditionally approved, or partially approved. As indicated above, EPA believes that the section 110 elements not connected with nonattainment plan submissions and not linked to the area's nonattainment status are not applicable requirements for purposes of review of the State's redesignation request. EPA also believes that since the part D requirements did not become due prior to Ohio's submittal of the final, complete redesignation request, they also are not applicable requirements for purposes of redesignation.

3. The Air Quality Improvements in Mahoning, Trumbull, and Columbiana Counties Are Due To Permanent and Enforceable Reductions in Emissions

We believe that the State of Ohio has adequately demonstrated that the observed air quality improvements in Mahoning, Trumbull, and Columbiana Counties are due to permanent and enforceable emission reductions resulting from the implementation of the SIP, Federal measures, and other State-adopted measures. In making this demonstration, the State has documented the changes in VOC and NO_X emissions from all anthropogenic (man-made or man-based) sources in Mahoning, Trumbull, and Columbiana Counties between 2002, an ozone standard violation year, and 2004, one of the years in which Mahoning, Trumbull, and Columbiana Counties recorded attainment of the 8-hour ozone standard. The Ohio EPA has also

discussed permanent and enforceable emission reductions have occurred elsewhere in the State and in other upwind areas that have contributed to the air quality improvement in Mahoning, Trumbull, and Columbiana Counties. Table 2 summarizes the VOC and NO_X emissions totals from the anthropogenic sources in 2002 and 2004 for all counties (Mahoning, Trumbull, Columbiana, and Mercer) in the nonattainment area as summarized in the State's ozone redesignation submittal. The Youngstown 8-hour ozone nonattainment area, which is a bi-state area, must show emission reductions across the entire area. The table shows all the counties in the area including the Ohio and Pennsylvania counties.

TABLE 2.—TOTAL ANTHROPOGENIC VOC AND NO_X EMISSIONS FOR 2002 AND 2004 IN MAHONING, TRUMBULL, AND COLUMBIANA COUNTIES, OHIO AND MERCER COUNTY, PENNSYLVANIA

[Tons per summer day]

	2002	2004
Mahoning, Trumbull, and Columbiana Counties Volatile Organic Compounds Emissions		
Total All Source Categories	70.51	64.60
Mahoning, Trumbull, and Columbiana Counties Nitrogen Oxides Emissions		
Total All Source Categories	95.53	82.50
Mercer County Volatile Organic Compounds Emissions		
Total All Source Categories	20.80	19.05
Mercer County Nitrogen Oxides Emissions		
Total All Source Categories	25.44	22.43
Combined Total for Youngstown/Warren/Sharon OH-PA VOCs	91.31	83.65
Combined Total for Youngstown/Warren/Sharon OH-PA NO_X	120.97	104.93

From the above table, it can be seen that the Youngstown area experienced decreases in VOC and NO_X anthropogenic emissions between 2002 and 2004. The State of Ohio concludes that the differences in the 2002 and 2004 emissions are due primarily to the implementation of permanent and enforceable emission control requirements. The State asserts that these emission reductions along with those occurring elsewhere in the State and in upwind areas have led to observed improvements in ozone air quality in the Youngstown area.

Also, the State notes a significant decline in regional NO_X emissions between 2002 and 2004 as the result of the implementation of State NO_X emission control rules for combustion sources, primarily Electric Generating Units (EGUs), in compliance with EPA's NO_X SIP call and acid rain control requirements under title IV of the CAA. Besides the NO_X emission reductions occurring within the State itself, the implementation of statewide NO_X emission control rules occurred in many States east of the Mississippi River. These emission reductions are assumed to have contributed significantly to the air quality improvements in the Youngstown area through the reduction of transported ozone and ozone precursors. The Youngstown area has several EGUs which show reductions between 2002 and 2004. The EGU NO_X emissions are reduced from 23.36 tons per year in 2002 to 17.93 tons per day in 2004. These reductions are documented in Table 23 of the Ohio submittal. In addition, the area has benefited from the NO_X emission reductions occurring throughout the State of Ohio and in the surrounding areas. These regional NO_X emission reductions are considered to be permanent and enforceable.

Besides the implementation of the regional NO_X emission controls, the State of Ohio notes that, in the mid-1990's, the State of Ohio promulgated statewide rules requiring Reasonably Available Control Techniques (RACT) for significant new sources of VOC emissions. The RACT rules have been implemented for significant new VOC sources locating in Ohio subsequent to the State's adoption of the rules. The Ohio rules are found in OAC Chapter 3745–21. Additional implemented, or soon to be implemented, emission control rules include several Federal rules: (1) Tier II emission standards for vehicles and gasoline sulfur content standards (promulgated by EPA in February 2000 and currently being implemented); (2) heavy-duty diesel engine emission control rules (promulgated by the EPA in July 2000 and currently being implemented); and, (3) clean air non-road diesel rule (promulgated by the EPA in May 2004 and currently being phased in through 2009). All of these rules have contributed to reducing VOC and NO_X emissions throughout the State of Ohio (and in other States surrounding Ohio) and will contribute to further, future emission reductions in Ohio.

The State of Ohio commits to maintain the existing VOC and NO_X emission controls after Mahoning, Trumbull, and Columbiana Counties are redesignated to attainment of the 8-hour ozone NAAQS, and these reductions are required to be maintained under the Ohio SIP.

4. Mahoning, Trumbull, and Columbiana Counties Have a Fully Approvable Ozone Maintenance Plan Pursuant to Section 175A of the CAA

In conjunction with its request to redesignate Mahoning, Trumbull, and Columbiana Counties to attainment of the 8-hour ozone NAAQS, Ohio submitted SIP revision requests to provide for maintenance of the 8-hour ozone NAAQS in the Youngstown area through 2018, exceeding the 10 year minimum maintenance period required by the CAA.

a. What Is Required in an Ozone Maintenance Plan?

Section 175A of the CAA sets forth the required elements of air quality maintenance plans for areas seeking redesignation from nonattainment to attainment of a NAAQS. Under section 175A, a maintenance plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after the Administrator approves the redesignation to attainment. Eight years after the redesignation, the State must submit a revised maintenance plan which demonstrates that maintenance of the standard will continue for 10 years following the initial 10 year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary, to assure prompt correction of any future NAAQS violations. The September 4, 1992, John Calcagni memorandum provides additional guidance on the content of maintenance plans. An ozone maintenance plan should, at minimum, address the following items: (1) The attainment VOC and NO_X emissions inventories; (2) a maintenance demonstration showing maintenance for the first 10 years of the maintenance period; (3) a commitment to maintain the existing monitoring network; (4) factors and procedures to be used for verification of continued attainment; and, (5) a contingency plan to prevent and/or correct a future violation of the NAAQS. The Ohio maintenance plan is designed to work in conjunction with Pennsylvania's maintenance plan to keep the Youngstown area in attainment for the 8-hour ozone NAAQS.

b. What Are the Attainment Emission Inventories for Mahoning, Trumbull, and Columbiana Counties?

Ohio EPA prepared VOC and NO_X emission inventories for Mahoning, Trumbull, and Columbiana Counties, including point (significant stationary sources), other (area sources, smaller and widely-distributed stationary sources), Marine, Aircraft, and Railroad (MAR) mobile sources, non-road (off-road) mobile sources, and on-road mobile sources for 2002 (the base nonattainment year), 2004 (the attainment year), 2009, and 2018 (the projected maintenance year). To develop the 2004, 2009, and 2018 emission inventories, the Ohio EPA projected the 2002 emissions applying various source category-specific growth factors and emission control factors. The State has documented how the 2002 base year emissions were derived and how these emissions were projected to derive the 2004, 2009, and 2018 emissions. The following summarizes the procedures and sources of data used by the Ohio EPA to derive the 2002 emissions.

i. Point Sources

The primary source of point source information was facility-specific emissions and source activity data collected annually by the State for sources covered by Title V [4] source permits. This information includes emissions, process rates, source operating schedules, emissions control data, and other relevant source information. The State also used emissions data provided by EPA's EGU emission inventory, maintained to support the NO_X SIP call emissions trading program and the acid rain control/trading program. The sources included in the 2002 point source emissions inventory were identified using Ohio's Title V STARS database system. The emissions included in this database are facility-reported actual emissions.

Ohio EPA defines point source emissions as those which occur at an identifiable stationary stack or vent. Point source emissions not emitted from discrete stacks or vents are defined to be fugitive emissions. Facility-specific fugitive emissions are also reported by each Title V facility and stored in the Title V STARS database.

Point source emissions included in the 2002 base year emissions inventory were provided to the Lake Michigan Air Directors Consortium (LADCO). LADCO applied temporal and spatial profiles to calculate July weekday emissions rates. The Mahoning, Trumbull, and Columbiana Counties' emissions derived from this set of emissions data were split into EGU emissions and non-EGU emissions for inclusion in the base year emissions inventory used to support the Mahoning, Trumbull, and Columbiana Counties ozone redesignation request.

ii. Area (Other) Sources

Area sources are those sources which are generally small, numerous, and have not been inventoried as specific point, mobile, or biogenic sources. The emissions for these sources are generally calculated using various surrogates, such as population, estimates of employees in various occupational groups, etc., and grouped by general source types. The area source emissions are typically defined at the county level.

Ohio EPA has either used published Emission Inventory Improvement Program (EIIP) emissions estimation methodologies or other methodologies typically used by other states to estimate the area source emissions. Area source categories include: Various stationary combustion sources (not including the EGU sources included in the point source portion of the emissions inventory); agricultural pesticides; architectural surface coatings; auto body refinishing; consumer and commercial solvent usage; solvent cleaning; fuel marketing; graphic arts; hospital sterilizers; industrial surface coating (minus point source emissions for this source category); municipal solid waste disposal; portable fuel containers; privately owned treatment works; traffic markings; human cremation; industrial fuel combustion; residential fuel combustion; structural fires; and miscellaneous source categories. The State has documented the data sources used for each of these source categories.

iii. Non-Road Mobile Sources

The non-road mobile source emissions inventory was generated regionally by running EPA's National Mobile Inventory Model (NMIM). LADCO applied spatial and temporal allocations to derive emissions for a July weekday. The basic non-road algorithm for calculating emissions in NMIM uses base year equipment populations, average load factors, available engine powers, activity hours and emission factors to calculate the emissions.

iv. Marine, Aircraft, and Rail (MAR) Sources

Due to the significance of the emissions from these mobile source types, the Ohio EPA has decided to treat these source categories separately from other non-road mobile sources. The MAR emissions include emissions from commercial marine, aircraft, and locomotive sources.

Commercial marine vessels consist of several different categories of vessel types. For each vessel type, there are unique engine types, emission rates, and activity data sets. The emissions inventory documentation lists the vessel types and activity data sources by vessel type, along with special distribution of each vessel type.

Locomotive activity was divided into various rail categories: Class I operations; Class II/III operations; passenger trains; commuter lines; and yard operations. Since Class I operations

[4] Title V of the CAA requires source-specific emission permits detailing all applicable emission control requirements and emission limits, as specified in the SIP, for each source facility covered by the State's Title V source permit program and requirements.

are expected to be the most significant rail operations in the three Counties, operators of Class I operations were queried for activity and emissions-related information for each railroad line. This approach provided for more specific estimates of emissions by railroad line. Class II/III emissions were based on national fuel consumption and per employee fuel consumption estimates. The number of railroad employees in each county was used to allocate the fuel consumption to each county and, therefore, the emissions to each county.

EPA provided the aircraft emission estimates based on Federal Aviation Administration (FAA) published Landing and Take-Off (LTO) rates by engine type for each airline and major airport in the State of Ohio. The LTO-engine information was combined with engine type-specific emission factors developed by the International Civil Aviation Organization (ICAO), and, through use of a FAA Emissions and Dispersion Modeling System (EDMS), emissions were calculated and assigned to each county in the State, including Mahoning, Trumbull, and Columbiana Counties.

The MAR data were processed by LADCO to calculate July 2002 daily emissions of VOC and NO_X.

v. On-Road Mobile Sources

The inventories of on-road mobile source emissions for Mahoning, Trumbull, and Columbiana Counties were developed by the Ohio EPA in conjunction with the Ohio Department of Transportation (Ohio DOT), the Eastgate Regional Council of Governments (Eastgate), LADCO, and EPA. Eastgate utilized a regional travel demand forecast model to simulate traffic and to forecast traffic flow for given growth expectations in the metropolitan areas of Mahoning and Trumbull counties. In rural areas that are not covered by the network model, such as Columbiana County, the Highway Performance Monitoring System (HPMS) data was used to estimate vehicle mile of travel (VMT). The travel demand forecasting model was used to predict the total daily vehicle miles traveled and speeds on roadways. MOBILE6.2 is used to calculate emissions per mile based on the VMT and speed projections from the travel demand forecast model. The most current vehicle age distribution data, temperature data and fuel properties data provided by Ohio EPA was used in the analysis.

vi. Projected Emissions for the Attainment Year

Ambient ozone air quality data showed that Mahoning, Trumbull, and Columbiana Counties met the 8-hour ozone NAAQS in the 2004–2006 period. Ohio EPA used emission estimates for 2004 as the ''attainment year'' emissions for the area, to represent the base period emissions for the demonstrations of maintenance. See the discussion of the demonstrations of maintenance below. The 2004 emissions were estimated by growing the emissions from the 2002 base year emission levels.

Ohio EPA used point source growth data provided by individual point source facilities along with other source category-specific growth estimates and emission control estimates to estimate stationary source VOC and NO_X emissions for Mahoning, Trumbull, and Columbiana Counties. LADCO provided growth and source control projection data to project VOC and NO_X area source emissions. The Metropolitan Planning Organization for the area, Eastgate, provided projections of vehicle travel estimates (Vehicle Miles Traveled (VMT)) and emissions, with MOBILE 6.2 providing the expected changes in vehicle emission factors. The estimated 2004 emissions have been compared to the 2002 base year emissions to demonstrate the basis for the improved air quality in Mahoning, Trumbull and Columbiana Counties. See Table 2 above for a summary of the 2004 VOC and NO_X emissions and for a comparison of these emissions with the 2002 emissions.

c. Demonstration of Maintenance

As part of the December 4, 2006, redesignation request submittal, Ohio EPA included requested revisions to the Ohio SIP to incorporate the ozone maintenance plan for Mahoning, Trumbull, and Columbiana Counties as required under section 175A of the CAA. Included in the maintenance plan is the ozone attainment maintenance demonstration. This demonstration shows maintenance of the 8-hour ozone NAAQS through 2018 by documenting attainment year and future projected VOC and NO_X emissions and showing that future emissions of VOC and NO_X will remain at or below the attainment year emission levels. Note that an ozone maintenance demonstration need not to be based on ozone modeling. See *Wall* v. *EPA*, 265 F.3d 426 (6th Cir. 2001), Sierra Club v. EPA, 375 F.3d 537 (7th Cir. 2004). See also 66 FR 53094, 53099–53100 (October 19, 2001) and 68 FR 25430–25432 (May 12, 2003).

The Ohio EPA projected the VOC and NO_X emissions in Mahoning, Trumbull, and Columbiana Counties to the years of 2009 and 2018 to demonstrate maintenance of the 8-hour ozone NAAQS for at least 10 years after the expected redesignation dates for these areas. For all counties, Ohio EPA used source growth estimates provided by LADCO along with mobile source growth estimates provided by the Eastgate travel demand model and MOBILE 6.2 to project the Mahoning, Trumbull, and Columbiana Counties VOC and NO_X emissions.

Table 3 summarizes the VOC and NO_X emissions projected to occur in Mahoning, Trumbull, and Columbiana Counties Ohio during the demonstrated maintenance period. The State of Ohio chose 2018 as a maintenance year to meet the 10-year maintenance requirement of the CAA, allowing several years for EPA to complete the redesignation rulemaking process. The State also chose 2009 as an interim year to demonstrate that VOC and NO_X emissions will remain below the attainment year levels throughout the 10-year maintenance period. Table 4 summarizes the VOC and NO_X emissions projected to occur in Mercer County, Pennsylvania over the same maintenance period.

TABLE 3.—PROJECTED VOC AND NO_X EMISSIONS IN MAHONING, TRUMBULL, AND COLUMBIANA COUNTIES, OHIO

[Tons/day]

Source sector	2004 Attainment	2009 Interim	2018 Maintenance	Safety margin
VOC Emissions:				
Point (includes EGU)	6.02	6.39	7.75	
Area (Other)	24.10	22.86	23.03	
Non-Road Mobile	7.95	6.24	4.90	
On-Road Mobile	26.21	17.03	9.01	

TABLE 3.—PROJECTED VOC AND NO_X EMISSIONS IN MAHONING, TRUMBULL, AND COLUMBIANA COUNTIES, OHIO—Continued

[Tons/day]

Source sector	2004 Attainment	2009 Interim	2018 Maintenance	Safety margin
Marine-Air-Railroad	0.32	0.29	0.29	.....
Total VOC Emissions	64.60	52.81	44.98	*19.62
NO_X Emissions:				
Point	20.25	8.32	12.69	.....
Area (Other)	2.49	2.79	2.96	.....
Non-Road Mobile	10.26	8.23	4.21	.....
On-Road Mobile	43.50	29.32	11.56	.....
Marine-Air-Railroad	6.00	4.30	4.01	.....
Total NO_X Emissions	82.50	52.96	35.43	*47.07

* Difference between 2004 attainment year emissions and 2018 maintenance year emissions.

TABLE 4.—PROJECTED VOC AND NO_X EMISSIONS IN MERCER COUNTY, PENNSYLVANIA

[Tons/day]

Source sector	2004 Attainment	2009 Interim	2018 Maintenance	Safety margin
VOC Emissions:				
Point	1.73	2.73	3.66	.....
Area (Other)	7.61	7.36	7.83	.....
Non-Road (includes MAR)	3.78	3.41	2.59	.....
On-Road Mobile	5.93	4.23	2.63	.....
Total VOC Emissions	19.05	17.73	16.71	*2.34
NO_X Emissions:				
Point	2.93	4.30	5.52	.....
Area (Other)	0.85	0.88	0.89	.....
Non-Road (includes MAR)	2.82	2.35	1.44	.....
On-Road Mobile	15.83	11.22	4.89	.....
Total NO_X Emissions	22.43	18.75	12.74	*9.69

* Difference between 2004 attainment year emissions and 2018 maintenance year emissions.

The Ohio EPA also notes that the State's EGU NO_X emissions control rules stemming from EPA's NO_X SIP call and Clean Air Interstate Rule (CAIR), to be implemented after 2006, will further lower NO_X emissions throughout the State and upwind of Mahoning, Trumbull, and Columbiana Counties. This will result in decreased ozone and ozone precursor transport into Mahoning, Trumbull, and Columbiana Counties, and will support maintenance of the 8-hour ozone standard.

The emissions projections for Mahoning, Trumbull, and Columbiana Counties, Ohio and Mercer County, Pennsylvania along with the expected impacts of the State's EGU NO_X control rules lead to the conclusion that the Youngstown area should maintain the 8-hour ozone NAAQS throughout the required 10-year maintenance period and through 2018. The projected decreases in local VOC and local and regional NO_X emissions indicate that peak ozone levels in the Youngstown area may actually further decline during the maintenance period.

Based on the comparison of the projected emissions and the attainment year emissions, we conclude that Ohio EPA has successfully demonstrated that the 8-hour ozone standard should be maintained in Mahoning, Trumbull, and Columbiana Counties. We believe that this is especially likely given the expected impacts of the NO_X SIP call and CAIR. This conclusion is further supported by the fact that other states in the eastern portion of the United States are also expected to reduce regional NO_X emissions through implementation of their NO_X emission control rules for EGUs and other NO_X sources through the implementation of the NO_X SIP call and CAIR.

d. Contingency Plan

Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the State will promptly correct a violation of the NAAQS that might occur after redesignation. The maintenance plan must identify the contingency measures to be considered for possible adoption, a schedule and procedure for adoption and implementation of the selected contingency measures, and a time limit for action by the State. The State should also identify specific indicators to be used to determine when the contingency measures need to be adopted and implemented. The maintenance plan must include a requirement that the State will continue to implement all measures with respect to control of the pollutant(s) that were included in the SIP before the redesignation of the area to attainment. See section 175A(d) of the CAA.

As required by section 175A of the CAA, Ohio has adopted contingency plans to help address possible future ozone air quality problems in the Youngstown area. The contingency plans have two levels of actions/responses depending on whether a violation of the 8-hour ozone standard is only threatened (Warning Level

Response), has actually occurred or appears to be very imminent (Action Level Response).

A Warning Level Response will be triggered whenever an annual (1-year) fourth-high monitored 8-hour ozone concentration of 88 ppb occurs in a single ozone season in the Youngstown area. A Warning Level Response will consist of a study to determine whether the high ozone value indicates a trend toward higher ozone concentrations or whether emissions appear to be increasing. The study will evaluate whether the trend, if any, is likely to continue and, if so, the control measures necessary to reverse the trend will be selected for evaluation and possible adoption. Implementation of necessary controls in response to a Warning Level Response triggering will take place as expeditiously as possible, but in no event later than 12 months from the conclusion of the most recent ozone season (September 30).

An Action Level Response will be triggered whenever a two year averaged annual fourth-high monitored 8-hour ozone concentration of 85 ppb occurs within the Youngstown area, or whenever a violation of the 8-hour ozone standard is actually monitored in either the Ohio or Pennsylvania portions of the Youngstown area. Ohio and Pennsylvania have agreed to work together to address any possible future violation of the 8-hour ozone standard. In the event that an Action Level Response is triggered and is not due to an exceptional event, malfunction, or noncompliance with a source permit condition or rule requirement, Ohio EPA will determine the additional emission control measures needed to assure future attainment of the ozone NAAQS. Emission control measures that can be implemented in a short time will be selected in order to be in place within 18 months from the close of the ozone season that prompted the Action Level Response. Any new emission control measure that is selected for implementation will be given a public review. If a new emission control measure is already promulgated and scheduled to be implemented at the Federal or State level and if that emission control measure is determined to be sufficient to address the ozone air quality problem, additional local measures may be unnecessary. Ohio EPA will submit to the EPA an analysis to assess whether the proposed emission control measures are adequate to reverse the increase in peak ozone concentrations and to maintain the 8-hour ozone standard in the maintenance area. The selection of emission control measures will be based on cost-effectiveness, emission reduction potential, economic and social considerations, or other factors that the Ohio EPA deems to be appropriate. Selected emission control measures will be subjected to public review and the State will seek public input prior to selecting new emission control measures. Finally, emission control measures that can be implemented in a short period of time will be selected in order to be in place within 18 months from the close of the ozone season in which the Action Level Response is triggered.

The State's redesignation request indicates that the contingency measures to be considered will be selected from a comprehensive list of measures deemed appropriate and effective at the time the selection is made (after the need for contingency measures is triggered). The selection of candidate contingency measures will be based on cost-effectiveness, emission reduction potential, economic and social considerations, and other factors that the Ohio EPA deems to be appropriate. Ohio will solicit input from interested and affected persons in the subject maintenance area prior to final selection of contingency measures.

Although it is not possible at this time to specify which contingency measures would actually be implemented, the Ohio EPA has listed possible contingency measures. These include:

- Low Reid vapor pressure gasoline;
- Tightening of RACT on existing sources covered by EPA Control Technique Guidelines issued in response to the 1990 Clean Air Act amendments;
- Application of RACT to smaller existing sources;
- One or more transportation control measures sufficient to achieve at least half of a percent reduction in actual area-wide VOC emissions. The transportation control measures to be considered include:
- Trip reduction programs, including: Employer-based transportation management plans; area-wide rideshare programs; work schedule changes; and telecommuting;
- Traffic flow and transit improvements; and
- Other new or innovative transportation measures not yet in widespread use that affected state and local governments deem appropriate;
- Alternative fuel and diesel retrofit programs for fleet vehicle operations;
- Controls on consumer products consistent with those adopted elsewhere in the United States;
- Requirements for VOC or NO_X emission offsets for new and modified major sources;
- Requirements for VOC or NO_X emission offsets for new and modified minor sources;
- Increase of the ratio of emission offsets required for new sources; and
- Requirements for VOC or NO_X emission controls on new minor sources (with emissions of less than 100 tons per year).

No contingency measures will be adopted and implemented without providing the opportunity for full public participation and comment in the contingency measure selection process.

A list of VOC and NO_X source types potentially subject to future emission controls include:

NO_X RACT:

- EGUs
- Asphalt batching plants
- Industrial/commercial and institutional boilers
- Process heaters
- Internal combustion engines
- Combustion turbines
- Other sources with NO_X emissions exceeding 100 tons per year

VOC RACT:

- Consumer products
- Architectural and industrial maintenance coatings
- Stage I gasoline dispensing facilities
- Automobile refinishing shops
- Cold cleaner degreasers
- Portable fuel containers
- Synthetic organic compound manufacturing
- Wood manufacturing
- Industrial wastewater
- Aerospace industry
- Ship building
- Bakeries
- Plastic parts coating
- Volatile organic liquid storage
- Industrial solvent cleaning
- Offset lithography
- Industrial surface coating
- Other VOC sources with emissions exceeding 50 tons per year.

e. Provisions for a Future Update of the Ozone Maintenance Plan

As required by section 175A(b) of the CAA, the State commits to review the maintenance plans 8 years after redesignation of Mahoning, Trumbull, and Columbiana Counties to attainment of the 8-hour ozone NAAQS as required by section 175A of the CAA.

We consider Ohio's ozone maintenance demonstration and contingency plan to be acceptable.

VI. Has Ohio Adopted Acceptable Motor Vehicle Emissions Budgets for the Ozone Maintenance Plan Which Can Be Used To Support Conformity Determinations?

A. How Are the Motor Vehicle Emission Budgets Developed and What Are the Motor Vehicle Emission Budgets for Mahoning, Trumbull, and Columbiana Counties?

Under the CAA, states are required to submit, at various times, SIP revisions and ozone maintenance plans for applicable areas (for ozone nonattainment areas and for areas seeking redesignations to attainment of the ozone standard or revising existing ozone maintenance plans). These emission control SIP revisions (e.g. reasonable further progress and attainment demonstration SIP revisions), including ozone maintenance plans, must create MVEBs based on on-road mobile source emissions that are allocated to highway and transit vehicle use that, together with emissions from other sources in the area, will provide for attainment or maintenance of the ozone NAAQS.

Under 40 CFR part 93, MVEBs for an area seeking a redesignation to attainment of the NAAQS are established for the last year of the maintenance plan (for the maintenance demonstration year). The State has the option to establish additional MVEBs for additional years as deemed appropriate by the interagency consultation process. The MVEBs serve as ceilings on mobile source emissions from an area's planned transportation system and are used to test planned transportation system changes or projects to assure compliance with the emission limits assumed in the SIP. The MVEB concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEBs in the SIP and how to revise the MVEBs if needed.

Under section 176(c) of the CAA, new transportation projects, such as the construction of new highways, must ''conform'' to (i.e., be consistent with) the part of the SIP that addresses emissions from cars, trucks, and other on-roadway vehicles. Conformity to the SIP means that transportation activities will not cause new air quality standard violations, or delay timely attainment of the NAAQS. If a transportation plan does not conform, most new transportation projects that would expand the capacity of the roadways cannot go forward. Regulations at 40 CFR Part 93 set forth EPA's policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities to a SIP.

The Transportation Conformity Rule, in 40 CFR 93.118(f), provides for adequacy findings through two mechanisms. First, 40 CFR 93.118(f)(1) provides for posting a notice to the EPA conformity Web site at: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm* and providing a 30-day public comment period. Second, a mechanism is described in 40 CFR 93.118(f)(2) which provides that EPA can review the adequacy of an implementation plan submission simultaneously with its review of the implementation plan itself. For this area, EPA is using the first process and posted the notice on our adequacy Web site on December 11, 2006. The comment period closed January 11, 2007, without any comments from the public on the adequacy of the MVEBs.

Both Ohio and Pennsylvania are establishing separate State budgets in the Ohio and Pennsylvania maintenance plans. When conducting transportation conformity determinations, the Eastgate Regional Council of Governments will use the budgets established for Mahoning, Trumbull, and Columbiana Counties. Mobile source emissions will be constrained by both the Ohio maintenance plan budgets and the budgets established for Mercer County by Pennsylvania. These budgets will assure that mobile source emissions do not increase and that the air quality remains below the 8-hour ozone NAAQS.

The Mahoning, Trumbull, and Columbiana Counties ozone maintenance plan contains VOC and NO_X MVEBs for the years 2009 and 2018. EPA has reviewed the submittal and has found that the MVEBs for Mahoning, Trumbull, and Columbiana Counties meet the adequacy criteria in the Transportation Conformity Rule.

EPA, through this rulemaking, is proposing to approve the MVEBs for Mahoning, Trumbull, and Columbiana Counties because EPA has determined that the budgets are consistent with the control measures and future emissions projected in the SIP and that Mahoning, Trumbull, and Columbiana Counties can maintain attainment of the 8-hour ozone NAAQS for the relevant required 10-year period with mobile source emissions at the levels of the MVEBs. Ohio EPA has determined the 2018 MVEBs for Mahoning, Trumbull, and Columbiana Counties to be 10.36 tons per day for VOC and 13.29 tons per day for NO_X and the 2009 MVEBs for Mahoning, Trumbull, and Columbiana Counties to be 19.58 tons per day for VOC and 33.71 tons per day for NO_X. These MVEBs exceed the on-road mobile source VOC and NO_X emissions projected by the Ohio EPA for 2009 and 2018, but do not exceed the levels necessary for continued maintenance of the NAAQS. Through discussions with all organizations involved in transportation planning for Mahoning, Trumbull, and Columbiana Counties, Ohio EPA decided to include 15 percent safety margins in the MVEBs to provide for mobile source growth not anticipated in the projected 2009 and 2018 emissions. Ohio EPA has demonstrated that Mahoning, Trumbull, and Columbiana Counties can maintain the 8-hour ozone NAAQS with mobile source emissions at the levels of the MVEBs since total source emissions with the increased mobile source emissions will remain under the attainment year levels. These MVEBs will be separate state area budgets for Mahoning, Trumbull, and Columbiana Counties, Ohio. Pennsylvania established MVEBs for Mercer County through the 8-hour ozone maintenance plan that was submitted with Pennsylvania's request for redesignation. Action on the Pennsylvania MVEBs will be taken through separate rulemaking.

B. What Is a Safety Margin?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan for a future maintenance year. As noted in Tables 3 and 4 above, Mahoning, Trumbull, and Columbiana Counties are projected to have a VOC safety margin of 22.42 tons per day and a NO_X safety margin of 47.07 tons per day in 2018. The addition of a portion of the safety margin to the MVEBs continues to maintain the emissions levels below the attainment level.

C. Are the MVEBs Approvable?

The 2009 and 2018 VOC and NO_X MVEBs for Mahoning, Trumbull, and Columbiana Counties (see Table 5) are approvable because they maintain the total emissions for Mahoning, Trumbull, and Columbiana Counties at or below the attainment year emission inventory levels, as required by the transportation conformity regulations.

TABLE 5.—MOTOR VEHICLE EMISSION BUDGETS FOR COLUMBIANA, MAHONING AND TRUMBULL COUNTIES, OHIO

Mahoning, Trumbull, and Columbiana Counties Ohio budgets	Year 2009	Year 2018
VOC (tons/day)	19.58	10.36
NO_X (tons/day)	33.71	13.29

VII. What Action Is EPA Taking?

EPA is proposing to make a determination that the Youngstown area is attainment the 8-hour ozone NAAQS and EPA is proposing to approve Ohio's maintenance plan for assuring that the area will continue to attain this standard. The maintenance plan demonstrates maintenance to the year 2018 and includes contingency measures to remedy possible future violations of the 8-hour ozone NAAQS, and establishes 2009 and 2018 MVEBs for these Counties. EPA is proposing to approve the 2018 MVEBs submitted by Ohio in conjunction with the redesignation request.

VIII. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, September 30, 1993), this action is not a ''significant regulatory action'' and, therefore, is not subject to review by the Office of Management and Budget.

Paperwork Reduction Act

This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Unfunded Mandates Reform Act

Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant regulatory action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272, requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impractical. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a program submission that otherwise satisfies the provisions of the Clean Air Act. Therefore, the requirements of section 12(d) of the NTTA do not apply.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: April 6, 2007.

Walter W. Kovalick,

Acting Regional Administrator, Region 5.

[FR Doc. E7–7352 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 07–1448, MB Docket No. 05–228; RM–11255]

Radio Broadcasting Services; Kiowa, KS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal.

SUMMARY: This document dismisses a pending petition for rulemaking filed by Charles Crawford to allot Channel 233A at Kiowa, Kansas for failure to state a continuing interest in the requested allotment. The document therefore terminates the proceeding.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 05–228, adopted March 28, 2007, and released March 30, 2007. The full text of this Commission decision is available for inspection and copying during normal

business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *www.BCPIWEB.com*.

This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of this Report and Order to Government Accountability Office, pursuant to the Congressional Review Act, *see* 5 U.S.C. Section 801(a)(1)(A) because the proposed rule is dismissed).

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. E7–7289 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 07–51; FCC 07–32]

Exclusive Service Contracts for Provision of Video Services in Multiple Dwelling Units and Other Real Estate Developments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission takes steps to encourage greater competition in the market for the delivery of multichannel video programming by soliciting comment on the use of exclusive contracts for the provision of video services to multiple dwelling units (''MDUs'') or other real estate developments. The Commission also seeks comment on whether the use of exclusive contracts in the MDU video provider market unreasonably impedes the achievement of the interrelated federal goals of enhanced multichannel video competition and accelerated broadband deployment and, if so, how the Commission should act to address that problem.

DATES: Comments for this proceeding are due on or before June 18, 2007; reply comments are due on or before July 18, 2007.

ADDRESSES: You may submit comments, identified by MB Docket No. 07–51, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Holly Saurer, *Holly.Saurer@fcc.gov* of the Media Bureau, Policy Division, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), FCC 07–32, adopted on March 22, 2007, and released on March 27, 2007. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC 20554. These documents will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Initial Paperwork Reduction Act of 1995 Analysis

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

Summary of the NPRM of Proposed Rulemaking

I. Introduction

In this Notice of Proposed Rulemaking (''NPRM''), we solicit comment on the use of exclusive contracts for the provision of video services to multiple dwelling units (''MDUs'') or other real estate developments. Greater competition in the market for the delivery of multichannel video programming is one of the primary goals of Federal communications policy. Moreover, for many participants in the marketplace, the ability to offer video to consumers and the ability to deploy broadband networks rapidly are linked intrinsically. However, potential competitors seeking to enter the multichannel video programming distributor (''MVPD'') marketplace have alleged that the use of exclusive contracts for the provision of video services to MDUs or other real estate developments serves as a barrier to entry. Accordingly, this *NPRM* is designed to solicit comment on whether the use of exclusive contracts in the MDU video provider market unreasonably impedes the achievement of the interrelated federal goals of enhanced multichannel video competition and accelerated broadband deployment and, if so, how the Commission should act to address that problem.

II. Background

1. In 1997, the Commission issued an NPRM regarding the use of exclusive access arrangements in MDUs. The Commission stated that exclusive service contracts between MDU owners and MVPDs could be considered pro-competitive or anti-competitive, depending upon the circumstances involved. Commenters who were effectively prohibited from providing service due to the existence of exclusive contracts argued that those contracts were anti-competitive. Other commenters argued that exclusive contracts were necessary to enhance their ability to recover investment costs. In the corresponding Report and Order, the Commission declined to take any action regarding exclusive agreements, concluding that there was insufficient evidence in the record to determine the extent of use of such exclusive contracts, and whether or not such contracts had significantly impeded access by competitive providers into the MDU market.

2. We note that the Commission is considering MDU access with respect to other services. In the context of

commercial telecommunications services, the Commission has prohibited the enforcement of exclusive access arrangements in multiple tenant environments (''MTEs''). In the *Competitive Networks Order*, the Commission concluded that a ban on exclusive contracts for telecommunications service in commercial MTEs would foster competition in that market. Unlike parties in the inside wiring proceeding, no party in the competitive networks proceeding argued in support of exclusive contracts in the commercial setting. Further, in *Competitive Networks FNPRM,* the Commission sought comment on other issues related to the imposition of a nondiscriminatory access requirement, including possibly extending the *Competitive Networks Order* findings to residential MTEs. We intend to issue a public notice seeking to refresh the record in that proceeding. Also, in the *Cox Inside Wiring* proceeding, the Commission is considering issues relating to the scope of competitors' right to access incumbent LECs' inside wire in multiunit premises for purposes of offering competing telephone service.

3. The Commission recently adopted a Report and Order (''*Franchising Reform Order*'') relating to Section 621 of the Act. The *Franchising Reform Order* adopted several provisions to remedy unreasonable local government procedures and behavior with respect to the franchising process that result in unreasonable refusals to grant additional competitive franchises. The NPRM in that proceeding asked for comment on the specific rules or guidance that we should adopt to ensure that the local cable franchising process does not unreasonably impede competitive entry. Among other issues, commenters discussed the impediment presented by the use of exclusive contracts for the provision of video services to MDUs and other real estate developments.

4. Specifically, SureWest Communications, which provides bundled offerings of voice, data, and video services, filed an *ex parte* statement asking the Commission to prohibit MVPDs from excuting new, or enforcing existing, exclusive access agreements with MDUs and other real estate developments. SureWest argues that exclusive agreements are used by incumbent providers to undercut the competitive market for video services and states that over 25% of the MDUs that its network passes are locked into exclusive agreements, which effectively bar SureWest from offering its services to residents in those MDUs. Manatee County, Florida submitted comments arguing that exclusive access agreements, if permitted at all, should be of limited duration. Manatee County stated that exclusive long-term contracts harm competition and permit incumbent providers to become complacent, imposing antiquated systems on their subscribers. The County noted that it recently adopted an ordinance which prohibits any of its franchisees from entering into exclusive agreements of more than five years. Verizon filed *ex parte* statements arguing that the Commission should prohibit MVPDs from entering into new, or enforcing existing, exclusive access agreements with owners of MDUs. Verizon stated that it had ''repeatedly encountered exclusive access arrangements which have prevented it from providing cable services to significant numbers of residents.'' Verizon provided examples of requests to cease and desist the marketing of its FiOS video service offerings (discussing various examples, including a cease and desist letter from Bright House Networks regarding marketing of FiOS in the River Chase apartment complex in Tampa, Florida; a letter from BDR Broadband, LLC regarding the provision of FiOS in apartment complexes in Plano and Carrollton, Texas; negotiations with Ariger Management in Maryland that have an exclusive contract with Comcast; and negotiations with Post Properties in Fairfax County, Virginia that have a perpetual contract with Cox). Verizon stated that some landlords would like to give tenants a greater variety of cable choices, but are unable to do so because of exclusive contracts. Further, Verizon notes that exclusive contracts do not provide video providers any incentives to upgrade equipment or improve services, which adversely impacts consumers. In contrast, the National Multi-Housing Council filed an *ex parte* statement urging the Commission to reject calls for regulation of exclusive access agreements, stating that exclusive contracts give competitive providers assurance that they will be able to recover the capital costs of installing their facilities, thereby increasing the prospects of competition.

III. Discussion

5. Potential competitive video providers have alleged that the use of exclusive contracts for MDUs or other real estate developments serves as a barrier to entry, and that these exclusive contracts unreasonably delay competitive entry. As noted in the *621 Order,* the video provider marketplace is currently undergoing a change, with the entrance of traditional phone companies that are primed to offer a ''triple play'' of voice, high-speed Internet access, and video services over their respective networks. Given the interrelated Federal goals of enhanced cable competition and rapid broadband deployment, we seek comment on a number of issues relating to the prevalence and use and effect of exclusive contracts in today's marketplace.

A. Potential Competitors' Current Ability to Obtain Access to MDUs

6. As an initial matter, we request comment on the current environment for MVPDs attempting to obtain access to MDUs or other real estate developments. To what extent do exclusive contracts impede the realization of our policy goals? How often have competitive entrants confronted exclusive access agreements, what are the terms of those agreements, and are those agreements becoming more prevalent? How has the multichannel video marketplace changed since adoption of our *Inside Wiring Report and Order*, and what effect have those changes had for consumers who live in MDUs or other real estate developments? What is the current status of state mandatory access laws and what impact do they have on the issues raised herein?

7. We also ask for additional information on the MVPDs operating pursuant to such exclusive contracts. In the *Inside Wiring Second Report and Order* we stated that exclusive contracts may benefit new entrants by reducing investment risk. Verizon indicates, however, that incumbent providers are soliciting such exclusive contracts when a potential competitor is actively seeking a local franchise to provide service in the MDU's franchise area. We seek comment on whether MVPDs seek exclusive contracts in an effort to frustrate competitive entry. Do incumbent providers use the time during which new entrants are negotiating local franchises in order to obtain exclusive contracts? We also seek comment on whether, in today's market, exclusive contracts benefit new entrants, incumbent providers, or both. We also ask whether the video providers entering into such exclusive contracts would be unable to provide service to these MDUs or other real estate developments absent the protections afforded by exclusive contracts.

B. The Commission's Authority to Prohibit the Use of Exclusive Contracts

8. We tentatively conclude that the Commission has authority to regulate exclusive contracts for the provision of

video services to MDUs or other real estate developments where we find that such contracts may impede competition and impair deployment of those services. We seek comment on this tentative conclusion, particularly with regard to our authority under, and the scope and applicability of, Section 628(b) of the Communications Act of 1934 and Section 706 of the 1996 Telecommunications Act. We also seek comment on the scope and applicability of Section 623, Section 1, Section 4(i), and Section 303(r) of the Communications Act of 1934 to this issue as well as other provisions that may provide us with authority to regulate exclusive contracts. We note that Section 628(b) states

> [i]t shall be unlawful for a cable operator, a satellite, cable programming vendor in which a cable operator has an attributable interest, or a satellite broadcast programming vendor to engage in unfair methods of competition or unfair or deceptive acts or practices, the purpose or effect of which is to hinder significantly or to prevent any multichannel video programming distributor from providing satellite cable programming or satellite broadcast programming to subscribers or consumers.

We also seek comment on how we should define what constitutes ''unfair methods of competition or unfair or deceptive acts or practices'' under Section 628(b). We note that this language is similar to that used in the Federal Trade Commission Act. Commenters should address the relevance to our interpretation of Section 628(b) of any interpretation of similar language by the FTC or Federal courts.

9. In addition, Section 706 of the 1996 Telecommunications Act, charges the Commission to ''encourage the deployment of * * * advanced telecommunications capability to all Americans.'' Given the relationship between a company's ability to offer video programming to customers and its ability to invest in broadband facilities, does Section 706 provide the Commission authority to address competitive concerns relating to exclusive contracts? Moreover, the Commission is empowered by Section 1 of the Act ''to execute and enforce the provisions of this Act,'' and by Section 4(i) ''to perform any and all acts, make such rules and regulations, and issue such orders, not inconsistent with this Act, as may be necessary in the execution of its functions.'' We also note that, with respect to MDU ''home run'' wiring, the Commission concluded that it had authority under Title VI (particularly Section 623) in conjunction with Sections 4(i) and 303(r) to regulate the disposition of such wiring upon termination of service. ''Home run'' wiring in an MDU is the wiring that runs from the demarcation point to the point at which the MVPD's wiring becomes devoted to an individual subscriber or individual loop. We invite commenters to address whether these provisions, or others, can or should serve as a basis for regulating exclusive contracts for the provision of video services to MDUs or other real estate developments. In addition, we ask parties to address the scope of the Commission's authority. Does the Commission have authority to regulate only exclusive contracts entered into after the effective date of the regulations or could it declare existing exclusive contracts void or voidable? Does the Commission have authority to regulate exclusive contracts entered into by MVPDs other than cable operators? Finally, we seek comment on the effect, if any, of state mandatory access laws or other statutory or constitutional considerations on the Commission's authority in this area.

C. Whether Commission Action Is Needed to Ensure Competitive Video Access to MDUs

10. We seek comment on the impact of exclusive contracts on consumer choice and video competition. We note that, in the context of telecommunications services, the Commission has prohibited the enforcement of exclusive access arrangements in commercial MDUs. Does the existence of exclusive contracts within a community reduce the likelihood of competitive entry in the community? What are the typical durations of existing exclusive contracts? Are the costs associated with providing service to MDUs or other real estate developments significantly more than the costs of providing service in other areas? Is there more risk associated with serving these types of developments? Are the marketing costs higher in these areas? Is customer churn higher? How do the prices and services offered under the exclusive contracts compare to those offered to other customers? Are additional payments made to or by the MVPD in return for exclusive contracts? Do existing exclusive contracts provide the MVPD with a right of first refusal when renegotiating the contract? To the extent that some exclusive contracts can be pro-competitive and benefit consumers, we seek comment on those circumstances. If the Commission determines that it would serve the public interest to regulate exclusive contracts, we seek comment on how we should regulate such contracts.

11. We seek comment on whether the Commission should limit exclusive contracts only where the video provider at issue possesses market power. In this regard, we call for comment on how the video programming market has changed since the issue was last posed in the *Inside Wiring FNPRM*, and whether the Commission should reconsider restriction or prohibition of the use of exclusive contracts by video providers with market power. In particular, we seek comment on how to define ''market power'' for these purposes. We also seek input on any other issues relevant to the analysis of market power and exclusive contracts. Does the competitive impact of exclusive contracts differ depending on whether a competing terrestrial MVPD was able to provide service to the MDU or other real estate development at the time the exclusive contract was negotiated?

12. We also call for comment regarding the existence of ''perpetual'' contracts. Perpetual contracts are contracts that grant the incumbent provider the right to maintain its wiring and provide service to the MDU for indefinite or very long periods of time, or for the duration of the cable franchise term, and any extensions thereof. Perpetual contracts present some of the same competitive issues as exclusive contracts, and were also discussed in the *Inside Wiring Report and Order*. Are perpetual contracts currently being executed? If so, are perpetual contracts anti-competitive, as they effectively bar any competitive entry, or are there instances in which the use of perpetual contracts does not impede our policy goals of enhanced cable competition and accelerated broadband deployment? Commenters should address the Commission's authority to nullify or otherwise regulate perpetual contracts.

13. We also solicit comment on the specific rules or guidance that we should adopt to ensure that exclusive contracts do not unreasonably impede competitive video entry. Should the Commission establish explicit rules to which contracting parties must adhere or specific guidelines for MVPDs? Are there certain practices that we should find unreasonable through rules or guidelines? If so, what are these practices?

IV. Procedural Matters

A. Initial Regulatory Flexibility Analysis

14. As required by the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the

possible significant economic impact on a substantial number of small entities of the proposals addressed in this *Notice of Proposed Rulemaking*. The IRFA is set forth in the Appendix. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines for comments on the *NPRM*, and they should have a separate and distinct heading designating them as responses to the IRFA.

B. Ex Parte Rules

15. *Permit-But-Disclose.* This proceeding will be treated as a ''permit-but-disclose'' proceeding subject to the ''permit-but-disclose'' requirements under section 1.1206(b) of the Commission's rules. *Ex parte* presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, ex parte or otherwise, are generally prohibited. Persons making oral ex parte presentations are reminded that a memorandum summarizing a presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one- or two-sentence description of the views and arguments presented is generally required. Additional rules pertaining to oral and written presentations are set forth in section 1.1206(b).

C. Filing Requirements

16. *Comment Information.* Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, *interested* parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

• *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov*. Filers should follow the instructions provided on the Web site for submitting comments.

• For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov*, and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response.

• *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

17. Availability of Documents. Comments, reply comments, and ex parte submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.

Initial Regulatory Flexibility Analysis

18. As required by the Regulatory Flexibility Act of 1980, as amended (the ''RFA''), the Commission has prepared this Initial Regulatory Flexibility Analysis (''IRFA'') of the possible significant economic impact of the policies and rules proposed in the Notice of Proposed Rulemaking (''NPRM'') on a substantial number of small entities. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM provided in paragraphs 17–18 of the item. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (''SBA''). In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Proposed Rules

19. The NPRM initiates a proceeding to investigate the use of exclusive contracts for the provision of video services to multiple dwelling units (''MDUs'') and other real estate developments, in order to further the interrelated goals of enhanced cable competition and accelerated broadband deployment. Specifically, the NPRM solicits comment on the existence of exclusive contracts for the provision of video services to MDUs and other real estate developments, and whether such exclusive contracts are ever pro-competitive, and if not, whether the Commission has authority to prohibit the use of such agreements.

Legal Basis

20. The NPRM asks whether the Commission has authority to regulate the use of exclusive contracts for the provision of video services to MDUs or other real estate developments. It specifically asks whether such authority can be found in Sections 1, 4(i), 303(r), 623 and 628(b) of the Communications Act of 1934, as amended, and Section 706 of the Telecommunications Act of 1996.

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

21. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental

jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (''SBA'').

22. *Small Businesses.* Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.

23. *Small Organizations.* Nationwide, there are approximately 1.6 million small organizations.

24. *Small Governmental Jurisdictions.* The term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States. We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.'' We assume that the villages, school districts, and special districts are small, and total 48,558. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. Thus, we estimate that most governmental jurisdictions are small.

25. The Commission has determined that the group of small entities possibly directly affected by our action consists of small governmental entities. In addition the Commission voluntarily provides, below, descriptions of certain entities that may be merely indirectly affected by any rules that may ultimately result from the NPRM.

Cable Operators

26. *Cable and Other Program Distribution.* The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged as third-party distribution systems for broadcast programming. The establishments of this industry deliver visual, aural, or textual programming received from cable networks, local television stations, or radio networks to consumers via cable or direct-to-home satellite systems on a subscription or fee basis. These establishments do not generally originate programming material.'' The SBA has developed a small business size standard for Cable and Other Program Distribution, which is: all such firms having $13.5 million or less in annual receipts. According to Census Bureau data for 2002, there were a total of 1,191 firms in this category that operated for the entire year. Of this total, 1,087 firms had annual receipts of under $10 million, and 43 firms had receipts of $10 million or more but less than $25 million. An additional 61 firms had annual receipts of $25 million or more. Thus, under this size standard, the majority of firms can be considered small.

27. *Cable Companies and Systems.* The Commission has also developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers, nationwide. The Commission determined that this size standard equates approximately to a size standard of $100 million or less in annual revenues. Industry data indicate that, of 1,076 cable operators nationwide, all but eleven are small under this size standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 7,208 systems nationwide, 6,139 systems have under 10,000 subscribers, and an additional 379 systems have 10,000–19,999 subscribers. Thus, under this second size standard, most cable systems are small.

28. *Cable System Operators.* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Industry data indicate that, of 1,076 cable operators nationwide, all but ten are small under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard. The Commission does receive such information on a case-by-case basis if a cable operator appeals a local franchise authority's finding that the operator does not qualify as a small cable operator pursuant to section 76.901(f) of the Commission's rules.

29. *Open Video Services.* Open Video Service (''OVS'') systems provide subscription services. As noted above, the SBA has created a small business size standard for Cable and Other Program Distribution. This standard provides that a small entity is one with $13.5 million or less in annual receipts. The Commission has certified approximately 25 OVS operators to serve 75 areas, and some of these are currently providing service. Affiliates of Residential Communications Network, Inc. (RCN) received approval to operate OVS systems in New York City, Boston, Washington, D.C., and other areas. RCN has sufficient revenues to assure that they do not qualify as a small business entity. Little financial information is available for the other entities that are authorized to provide OVS and are not yet operational. Given that some entities authorized to provide OVS service have not yet begun to generate revenues, the Commission concludes that up to 24 OVS operators (those remaining) might qualify as small businesses that may be affected by our action.

Telecommunications Service Entities

30. As noted above, a ''small business'' under the RFA is one that, inter alia, meets the pertinent small business size standard (*e.g.*, a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not ''national'' in scope.

31. Wired Telecommunications Carriers. The SBA has developed a small business size standard for wireline firms within the broad economic census category, ''Wired Telecommunications Carriers.'' Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees. Census Bureau data for 2002 show that there were 2,432 firms in this category that operated for the entire year. Of this total, 2,395 firms had employment of 999 or fewer employees, and 37 firms had employment of 1,000 employees or more. The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with ''1000 employees or more.'' Thus, under this category and associated small business size standard, the majority of firms can be considered small.

Dwelling Units

32. *MDU Operators.* The SBA has developed definitions of small entities for operators of nonresidential buildings, apartment buildings, and dwellings other than apartment buildings, which include all such companies generating $6 million or less in revenue annually. According to the Census Bureau, there were 31,584 operators of nonresidential buildings generating less than $6 million in revenue that were in operation for at least one year at the end of 1997. Also according to the Census Bureau, there were 51,275 operators of apartment dwellings generating less than $6 million in revenue that were in operation for at least one year at the end of 1997. The Census Bureau provides no separate data regarding operators of dwellings other than apartment buildings, and we are unable at this time to estimate the number of such operators that would qualify as small entities.

Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

33. We anticipate that any rules that result from this action would have at most a *de minimis* compliance burden on cable operators and telecommunications service entities. Any rules that might be adopted pursuant to this NPRM likely would not require any reporting or recordkeeping requirements.

Steps Taken To Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered

34. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

35. As discussed in the NPRM, the Commission has initiated this proceeding to ensure that use of exclusive contracts for the provision of video services to MDUs and other real estate developments are pro-competitive. As noted above, applying any rules regarding the use of exclusive contracts in the provision of video services to MDUs or other real estate developments likely would have at most a *de minimis* impact on small governmental jurisdictions. We seek comment on the impact that any rules might have on such small governmental entities, as well as the other small entities described, and on what effect alternative rules would have on those entities. For instance, should a definition of ''market power,'' if such a definition is appropriate, make reference to small entities? We also invite comment on ways in which the Commission might impose restrictions on the use of exclusive contracts for the provision of video services while at the same time imposing lesser burdens on small entities.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

36. None.

V. Ordering Clauses

37. Accordingly, it is ordered that, pursuant to Sections 1, 4(i), 303(r), 623 and 628(b) of the Communications Act of 1934, as amended, and Section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 154(i), 303(r), 543, 548(b) and 157, this Notice of Proposed Rulemaking is hereby adopted.

38. It is further ordered that the Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E7–7254 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 070402075–7075–01; I.D. 022807F]

RIN 0648–AU73

Fisheries Off West Coast States; Highly Migratory Species Fisheries

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues a proposed rule to amend vessel identification regulations of the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species (HMS FMP). The current regulatory text requires all commercial fishing vessels and recreational charter vessels to display their official numbers on the port and starboard sides of the deckhouse or hull, and on an appropriate weather deck (horizontal or flat surface) so as to be visible from enforcement vessels and aircraft. The proposed rule would amend the regulatory text to provide an exemption to HMS recreational charter vessels in complying with the vessel identification requirements. The regulation is necessary to clarify that vessel identification requirements apply to HMS commercial fishing vessels and not to HMS recreational charter vessels.

DATES: Comments must be received by May 18, 2007.

ADDRESSES: You may submit comments on this proposed rule, I.D. 022807F, by any of the following methods:

- E-mail: *0648–AU73.SWR@noaa.gov*. Include the I.D. number in the subject line of the message.
- Federal eRulemaking Portal: *www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802 4213.
- Fax: (562) 980 4047.

FOR FURTHER INFORMATION CONTACT: Craig Heberer, Sustainable Fisheries Division, NMFS, 760–431–9440, ext. 303.

SUPPLEMENTARY INFORMATION: On April 7, 2004, NMFS published a final rule to implement the HMS FMP (69 FR 18444) that included regulatory text in 50 CFR 660.704 requiring display of vessel identification markings for commercial fishing vessels and recreational charter fishing vessels that fish for HMS off or land HMS in the States of California, Oregon, and Washington. The identification markings are consistent in size, shape, and location with vessel identification markings required on commercial fishing vessels operating under the Pacific Fishery Management Council's (Council) Groundfish Fishery Management Plan. The marking requirements at 50 CFR 660.704(b) state that the official number must be affixed to each vessel in block Arabic numerals at least 10 inches (25.40 cm) in height for vessels more than 25 ft (7.62 m) but equal to or less than 65 ft (19.81 m) in

length; and 18 inches (45.72 cm)in height for vessels longer than 65 ft (19.81 m) in length. Markings must be legible and of a color that contrasts with the background.

As discussed during the HMS FMP Plan Development phase, the Council's intent in recommending the current requirement, was to address marking for identification purposes on HMS commercial fishing vessels, not recreational charter vessels. Our intent in promulgating the rule was to exempt recreational charter vessels from the marking requirements, similar to exemptions granted under the Council's Groundfish FMP. The current inclusion of HMS recreational charter vessels as part of the vessel identification requirements in the HMS FMP is not consistent with how vessel marking requirements are applied in the Groundfish FMP. The Council recommended to NMFS that meeting this requirement was not necessary as the HMS recreational charter vessels were already adequately marked, under existing state and U.S. Coast Guard regulations, so as to be identified by enforcement assets from both air and sea. In addition to being unnecessary for enforcement purposes, compliance with the current marking requirement would detract from the aesthetics of the charter vessels and degrade the ''attraction factor'' for future clients.

Classification

NMFS has determined that the proposed rule is consistent with the HMS FMP and preliminarily determined that this proposed rule is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Approximately 327 vessels were permitted under the HMS FMP to operate in the HMS recreational charter fishery off the U.S. West Coast in 2006. This proposed rule would exclude owners of HMS permitted recreational charter vessels from the vessel identification regulations at 50 CFR 660.704. The cost of maintaining/applying the identification numbers is approximately one and one-half hours of labor and the cost of approximately 3 gallons of marine paint, or about $20. All vessels affected by this rule are considered small business entities; the rule should not only have no adverse economic impact to them, but should have a direct positive impact to them (i.e., it simply would relieve a burden).

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: April 13, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is proposed to be amended as follows:

PART 660—FISHERIES OFF THE WEST COAST STATES

1. The authority citation for part 660 continues to read as follows:

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

2. Section 660.704 is revised to read as follows:

§ 660.704 Vessel identification.

(a) *General.* This section only applies to commercial fishing vessels that fish for HMS off or land HMS in the States of California, Oregon, and Washington. This section does not apply to recreational charter vessels that fish for HMS off or land HMS in the States of California, Oregon, and Washington.

(b) *Official number.* Each fishing vessel subject to this section must display its official number on the port and starboard sides of the deckhouse or hull, and on an appropriate weather deck so as to be visible from enforcement vessels and aircraft.

(c) *Numerals.* The official number must be affixed to each vessel subject to this section in block Arabic numerals at least 10 inches (25.40 cm) in height for vessels more than 25 ft (7.62 m) but equal to or less than 65 ft (19.81 m) in length; and 18 inches (45.72 cm)in height for vessels longer than 65 ft (19.81 m) in length. Markings must be legible and of a color that contrasts with the background.

[FR Doc. E7–7381 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 070322067–7067–01; I.D. 031407A]

RIN 0648–AU03

Fisheries of the Exclusive Economic Zone Off Alaska; Prohibited Species Bycatch Management

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

ACTION: Proposed rule.

SUMMARY: NMFS proposes to amend regulations governing salmon bycatch in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to enhance the effectiveness of salmon bycatch measures by (1) exempting pollock vessels from Chinook and chum salmon savings area closures if they participate in an inter-cooperative agreement (ICA) to reduce salmon bycatch, and (2) exempting vessels participating in non-pollock trawl fisheries from chum salmon savings area closures because these fisheries intercept minimal amounts of salmon. The proposed rule is intended to promote the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP).

DATES: Written comments must be received by June 4, 2007.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian, Records Officer. Comments may be submitted by any of the following methods:

- E-mail: *0648–au03–BSA84–A-PR@noaa.gov*. Include in the subject line the following identifier: BS salmon proposed rule. E-mail comments, with or without attachments, are limited to 5 megabytes;
- Federal e-Rulemaking Portal: *http:www.regulations.gov*;
- Mail to P.O. Box 21668, Juneau, AK 99802;
- Fax: to (907) 586–7557; or
- Hand Delivery to the Federal Building, 709 West 9th Street, Room 420A, Juneau, AK.

Copies of the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) prepared for this action

may be obtained from the same mailing address listed here or from the NMFS Alaska Region Web site at www.fakr.noaa.gov.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to NMFS at ADDRESSES above and by e-mail to *David_Rostker@omb.eop.gov*, or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Jason Anderson, 907–586–7228, or *jason.anderson@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

NMFS manages the U.S. groundfish fisheries of the BSAI in the Exclusive Economic Zone under the FMP. The North Pacific Fishery Management Council (Council) prepared the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations implementing the FMP appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at subpart H of 50 CFR part 600.

Pacific salmon are caught incidentally in the BSAI trawl fisheries, especially in the pollock fishery. Of the five species of Pacific salmon, Chinook salmon (*Onchorynchus tshawytscha*) and chum salmon (*O. keta*) are most often incidentally caught in the pollock fishery. Pacific salmon are placed into two categories for purposes of salmon bycatch management: Chinook and non-Chinook. The non-Chinook category is comprised of chum, sockeye (*O. nerka*), pink (*O. gorbuscha*), and coho (*O. kisutch*) salmon. However, from 2001 through 2004, chum salmon represented about 98 percent of non-Chinook salmon harvested incidentally in the pollock trawl fisheries. For convenience, all non-Chinook salmon are referred to as chum salmon.

To address Chinook salmon bycatch concerns, the Council adopted several management measures designed to reduce overall Chinook salmon bycatch in the BSAI trawl fisheries. In 1995, the Council adopted, and NMFS approved, Amendment 21b to the FMP. Based on historic information on salmon bycatch, Amendment 21b established a Chinook salmon savings area (60 FR 31215, November 29, 1995). Under Amendment 21b, the Chinook salmon savings area closed when the incidental catch of Chinook salmon in BSAI trawl fisheries reached 48,000 fish. Amendment 58 to the FMP revised the Chinook salmon savings area measures (65 FR 60587, October 12, 2000). Amendment 58 reduced the Chinook salmon bycatch limit from 48,000 fish to 29,000 fish, mandated year-round accounting of Chinook bycatch in the directed pollock fishery, revised the boundaries of the Chinook salmon savings area closure, and implemented new closure dates. The timing of the closure depends on when the limit is reached. If the limit is reached:

- Before April 15, the area closes immediately through April 15. After April 15, the area re-opens, but closes again from September 1 through December 31.
- Between April 15 and September 1, the area would close from September 1 through the end of the year.
- After September 1, the area closes immediately through the end of the year.

The Chinook salmon savings area was further modified by Amendment 82 to the FMP (70 FR 9856, March 1, 2005). Amendment 82 established a separate Aleutian Islands subarea bycatch limit that, when reached, closes the existing Chinook salmon savings area located in the Aleutian Islands subarea (Area 1). The Chinook salmon savings area located in the Bering Sea subarea remained unchanged, but was designated as Area 2.

The Council also adopted a time-area closure designed to reduce overall chum salmon bycatch in the BSAI trawl fisheries. In 1995, Amendment 35 to the FMP established the chum salmon savings area (60 FR 34904, July 5, 1995). This area is closed to all trawling from August 1 through August 31 of each year. Additionally, if 42,000 chum salmon are caught in the Catcher Vessel Operational Area (CVOA) during the period August 15 through October 14, the area remains closed for the remainder of the calendar year.

Community development quota (CDQ) groups receive, along with allocations of groundfish CDQ, individual allocations of Chinook and non-Chinook annual bycatch amounts. Vessels groundfish CDQ fishing are not subject to the chum and Chinook salmon savings area closures that apply to the non-CDQ pollock fisheries. Rather, the Chinook salmon savings area closes to vessels directed fishing for pollock for a CDQ group once that CDQ group has reached its Chinook salmon bycatch limit. The chum salmon savings area closes to vessels using trawl gear to fish for groundfish CDQ once that CDQ group has reached its non-Chinook salmon bycatch limit. Thus, individual CDQ groups are subject to salmon savings area closures based on their respective catch of chum or Chinook salmon while groundfish CDQ fishing.

The Chinook and chum salmon savings areas were adopted based on historic observed salmon bycatch rates and were designed to avoid high spatial and temporal levels of salmon bycatch. From 1990 through 2001, the BSAI salmon bycatch average was 37,819 Chinook and 69,332 chum annually. Recently, however, salmon bycatch numbers have increased substantially. In 2003, 54,911 Chinook salmon and 197,091 chum salmon were taken incidentally in the trawl fisheries. In 2004, salmon bycatch increased substantially to 62,493 Chinook and 465,650 chum salmon. Bycatch amounts remained high in 2005 and totaled 67,541 Chinook and 116,999 chum salmon.

Since its establishment in 1995, the Chinook salmon savings area closure only has been triggered since 2003. The Chinook salmon bycatch limit was not reached prior to 2003. In 2003, the Chinook salmon savings area closed to directed trawl fishing for non-CDQ pollock on September 1, with the closure remaining in effect until the end of the calendar year. In 2004, the Chinook salmon savings area closed to directed trawl fishing for non-CDQ pollock on September 5 through the end of the year. In 2005, the Chinook salmon savings area in the Bering Sea subarea was closed to directed trawl fishing for non-CDQ pollock on September 1 through the end of the year.

Since establishment of the chum salmon savings area in 1995, the bycatch of non-Chinook salmon triggered closures in 2002, 2003, 2004, and 2005. In these years, the chum salmon savings area closed to non-CDQ trawl fisheries in September and October.

Anecdotal information from participants in the BSAI trawl fisheries indicated that salmon bycatch rates may be higher outside the Chinook and chum salmon savings area. In February 2005, the Council initiated an EA/RIR/IRFA to explore alternatives to the current salmon bycatch measures. Spatial and temporal comparisons of non-CDQ vessels fishing outside of the salmon savings areas with CDQ vessels fishing inside of the salmon savings areas indicated that bycatch rates were much higher outside of the savings areas.

In October 2005, the Council adopted Amendment 84 to the FMP. Amendment 84 would exempt non-CDQ and CDQ pollock vessels participating in a salmon bycatch reduction ICA from closures of the Chinook and chum salmon savings areas in the Bering Sea. Additionally, vessels participating in trawl fisheries for species other than

pollock would be exempt from chum salmon savings area closures. The Council and NMFS intend to use NMFS salmon bycatch information to assess the effectiveness of regulations implementing Amendment 84 at reducing salmon bycatch in the directed pollock fisheries. The Council also asked for participants in the salmon bycatch reduction ICA to report annually on how effective the ICA appears to be at reducing salmon bycatch. The Council also will gather additional information to assess the effectiveness of the ICA in coordinating voluntary salmon bycatch reduction efforts by participants in the Bering Sea pollock fisheries. Additionally, this information could be used to further assess whether participants fishing in the current salmon savings areas continue to encounter lower salmon bycatch rates than participants fishing outside of salmon savings areas.

The Council is also developing a separate FMP amendment that could result in additional management measures to reduce salmon bycatch. These measures could include altering the geographic coordinates of the Chinook and chum salmon savings areas based on recent bycatch rates, and implementing an individual salmon bycatch accountability program. However, the Council determined that consideration of these management measures would require additional time and chose to expedite Amendment 84 while the Council develops the second amendment.

Salmon Bycatch Reduction ICA

Amendment 84 proposes a management program intended to enable the pollock fleet to utilize its internal cooperative structure to reduce salmon bycatch. If Amendment 84 is approved and implemented, salmon savings area closures would not apply to vessels that operate under a salmon bycatch reduction ICA. Rather, the agency intends that salmon bycatch would be reduced as ICA parties comply with the provisions of the ICA. The ICA, including its enforcement mechanism, is discussed further below.

The salmon bycatch reduction ICA is intended to reduce salmon bycatch in the BSAI non-CDQ and CDQ pollock fisheries. American Fisheries Act (AFA) pollock fishery participants would incorporate the ICA into existing cooperative agreements.

CDQ groups, western Alaska community organizations, and AFA cooperatives would be eligible to become parties to the ICA. Parties to the ICA could include the following AFA cooperatives: Pollock Conservation Cooperative, the High Seas Catchers Cooperative, the Mothership Fleet Cooperative, the Inshore Cooperatives (Akutan Catcher Vessel Association, Arctic Enterprise Association, Northern Victor Fleet Cooperative, Peter Pan Fleet Cooperative, Unalaska Fleet Cooperative, Unisea Fleet Cooperative and Westward Fleet Cooperative) and all six CDQ groups. Additionally, western Alaskan groups who have an interest in the sustainability of salmon resources could be parties in the ICA. The ICA must identify at least one third party group representing western Alaskans who depend on salmon and have an interest in salmon bycatch reduction.

The purpose of the ICA would be to use real-time salmon bycatch information to avoid high incidental catch rates of chum and Chinook salmon. The ICA would be a contractual agreement among the parties. All parties to the ICA would agree to comply with ICA provisions, including requirements to retain the services of a private contractor to collect and analyze bycatch data and report salmon bycatch information to the ICA parties.

The ICA would require that the third party hired to facilitate salmon bycatch avoidance compare the bycatch rate of a participating cooperative to a pre-determined bycatch rate (base rate). All ICA provisions for fleet bycatch avoidance behavior, closures, and enforcement would be based on the ratio of the cooperative's rate to the base rate.

The third party entity hired to facilitate salmon bycatch avoidance would assign an ICA cooperative to one of three tiers based on its bycatch rate relative to the base rate. Higher tiers correspond to higher bycatch rates. Tier assignments determine access privileges to specific fishing areas. The ICA would prohibit a participant assigned to a high tier from fishing in a relatively larger geographic area to avoid high bycatch areas. Conversely, the ICA would grant access to a wider range of fishing areas to a participant assigned to a low tier based on fishing behavior that results in relatively low bycatch. The contractor would track bycatch rates for each participant. The ICA would specify a participant's tier assignment each week based on that participant's bycatch rate for the previous week. Thus, participants would have incentives to avoid fishing behavior that results in high bycatch rates.

Monitoring and enforcement would be facilitated through the ICA. Any of the parties to the ICA may bring civil suit or initiate a binding arbitration action against another party for violating the ICA. For example, a participant that fishes for pollock in a prohibited area based on its tier assignment would be subject to a monetary penalty. The ICA would include a penalty schedule for violating these tier closures.

As described above, two western Alaska salmon user groups could be parties to the ICA. These groups do not participate in commercial groundfish fisheries off Alaska. However, they represent subsistence salmon users, and are concerned about the amount of salmon bycatch taken in the groundfish fisheries. Because their members are partially dependent on healthy salmon returns, the western Alaska user groups have incentives to reduce salmon bycatch in the groundfish fisheries and monitor performance of the ICA's bycatch reduction measures. The Council's intent is that their participation in the ICA may improve monitoring and compliance among the parties. If either of these western Alaska user groups determines that fishing is not in compliance with the ICA, the user group could bring civil suit against the offending parties.

Chum Salmon Savings Area Exemption

Vessels participating in non-pollock trawl fisheries currently are subject to the chum salmon savings area closure. However, the best available information summarized in the EA/RIR/IRFA prepared for this action indicates that 97 percent of the 2002 and 2003 chum salmon bycatch occurred in the pollock fisheries. Because the non-pollock trawl sector accounts for such a small portion of the chum bycatch, the Council recommended exempting all non-pollock trawl vessels from the chum salmon savings area closure. While this proposed rule would exempt non-pollock trawl vessels from this closure, any chum salmon bycatch by these vessels would continue to contribute towards triggering closures.

Proposed Changes to Regulations

The salmon bycatch reduction ICA would be defined at § 679.2 as a voluntary civil agreement among pollock cooperatives, CDQ groups, and western Alaska subsistence salmon user groups that is intended to coordinate the pollock fishery in a manner that reduces incidental catch rates of salmon.

Prohibitions at § 679.7 would be revised to incorporate the primary elements of this proposed action into two existing prohibitions specific to CDQ fisheries. Section 679.7(d)(9) and (10) would be revised to extend the exemptions from salmon savings area closures to vessels participating in the pollock CDQ fishery under a salmon

bycatch reduction ICA. Additionally, §§ 679.7(d)(10), 679.21(e)(7)(vii), and 679.22(a)(10) would be revised to exempt trawl vessels directed fishing for groundfish other than pollock from the chum salmon savings area closure.

Regulations at §§ 679.21(e)(7)(ix) would be revised to exempt pollock trawl vessels participating in a salmon bycatch reduction ICA from closures in Area 2 of the Chinook salmon savings area. Vessels that are not participating in the salmon bycatch reduction ICA would remain subject to Chinook and chum salmon savings area closures.

As noted above, NMFS would not enforce provisions of the salmon bycatch reduction ICA. However, these proposed regulations would require the ICA to include basic provisions necessary to reduce salmon bycatch in the pollock fisheries. Additionally, NMFS would review the ICA for compliance with regulations. An ICA that includes these basic provisions would be approved by NMFS. If NMFS does not approve an ICA, participants would be able to appeal that determination, subject to current regulations at § 679.43. The process for submitting and obtaining NMFS approval of an ICA would be described at § 679.21(g). Additionally, § 679.21(g)(4) would establish an initial deadline of December 1, 2007, for the 2008 fishing year, and the ICA would remain in effect until it expires or is amended. An amendment of the ICA would require submission of an amended ICA signed by all parties and approval by final agency action of the amended ICA by NMFS.

Minimum requirements for an ICA would be described at § 679.21(g)(6). The proposed rule would require the salmon bycatch reduction ICA to list the parties to the agreement, describe how participants would avoid salmon bycatch in directed pollock fisheries, and describe internal monitoring and enforcement mechanisms for the ICA. It would require the ICA to identify at least one private firm retained to facilitate bycatch avoidance behavior and information sharing. It would require the ICA to dictate salmon bycatch avoidance behaviors for vessel operators subject to the ICA. In addition, it would require the ICA to specify a salmon bycatch base rate, a method for assigning a cooperative or CDQ group to one of three tiers based on its salmon bycatch rate relative to the salmon bycatch base rate and provisions for governing access to fishing areas by cooperatives or CDQ groups assigned to each tier. Finally, it would require the ICA to require all parties to comply with the provisions of the ICA.

The proposed rule also would require the ICA to include the names, Federal fisheries permit numbers, and United States Coast Guard (USCG) vessel identification numbers of vessels subject to the salmon bycatch reduction ICA. Finally, the proposed rule would require the ICA to list the name, business address, and phone number of the person who will annually file the ICA with NMFS.

The proposed rule also would require participants to procure an external compliance audit. If the compliance audit reveals a previously unidentified violation of the terms of the ICA, the information used to determine that this violation occurred would be required to be disseminated to all participants. Furthermore, if a violation of the ICA is identified at any time, but a penalty is not assessed, the information used to identify that violation would be required to be disseminated to all participants. These provisions are intended to increase transparency for the participants, and allow each participant to monitor compliance with the terms of the ICA.

If the Council determined that the salmon bycatch reduction ICA did not effectively reduce salmon bycatch, it could initiate a separate action to accomplish salmon bycatch reduction goals. Additionally, NMFS is concerned about the effective execution of the terms and conditions of the ICA. To address these concerns, regulations at § 679.61(f)(2)(vi) would require AFA annual reports to include the number of violations of the ICA, the nature of those violations, and the penalty imposed, if any, against the violating party.

Public comments are being solicited on the FMP amendment through the end of the comment period stated in the NOA. Public comments on the proposed rule must be received by the end of the comment period on the amendment, as published in the NOA, to be considered in the approval/disapproval decision on the amendment. All comments received by the end of the comment period on the amendment, whether specifically directed to the amendment, or the proposed rule, will be considered in the approval/disapproval decision. Comments received after that date will not be considered in the approval/disapproval decision on the amendment. To be considered, comments must be received by close of business on the last day of the comment period; that does not mean postmarked or otherwise transmitted by that date.

Classification

At this time, NMFS has not determined that the FMP/amendment that this rule would implement is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws. NMFS, in making that determination, will take into account the data, views, and comments received during the comment period.

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

NMFS prepared an initial regulatory flexibility analysis (IRFA) as required by section 603 of the Regulatory Flexibility Act. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of the preamble and in the **SUMMARY** section of the preamble. A copy of the IRFA is available from NMFS (see **ADDRESSES**). A summary of the analysis follows.

This action proposes to exempt vessels participating in directed pollock fishing from Chinook and chum salmon savings area closures if they participate in a salmon bycatch reduction ICA. The ICA is intended to reduce salmon bycatch in the BSAI AFA and CDQ pollock fisheries. Additionally, this proposed rule would exempt all non-pollock trawl vessels from the chum salmon savings area closure.

In 2003, about 116 trawl catcher vessels operated in the BSAI with gross revenues less than $3.5 million. NMFS records indicate that 112 BSAI catcher vessels were members of AFA cooperatives. Because of Small Business Administration affiliation guidelines, all AFA vessels are considered large entities. Therefore, four BSAI trawl catcher vessels appear to qualify as small entities. Additionally, NMFS' 2003 data indicates that three non-AFA catcher processor trawl vessels had gross revenues less than $3.5 million.

Alternative 1, the status quo, has resulted in increases in salmon bycatch in the Bering Sea pollock trawl fishery in recent years. This translates into foregone salmon value, assuming full terminal harvest of salmon bycatch, of nearly $1 million for Chinook and more than $250 thousand for chum in 2003. These values very likely overstate the actual harvest that might have occurred if salmon bycatch had not been taken in the Bering Sea pollock trawl fishery. Unfortunately, it is not possible to estimate actual harvest value more accurately at this time. However, the increases in salmon bycatch under the status quo likely results in increases in foregone value and decreased benefits of bycatch reduction. The status quo could also lead to future restrictions on the

Bering Sea pollock trawl fleet to reduce the incidental take of Chinook salmon listed under the Endangered Species Act.

Alternative 2 would eliminate the salmon savings closure areas altogether. The result would likely be reduced operational costs, improved vessel safety, improved product quality, and reduced management and enforcement costs. However, in the absence of any bycatch reduction measures this alternative may result in further increase in salmon bycatch in the Bering Sea pollock trawl fishery. Were that to occur, the foregone value of such bycatch would increase and the associate benefits of bycatch reduction would decrease, possibly dramatically. This could also result in the increased take of listed Chinook salmon in the Bering Sea pollock trawl fisheries.

Alternative 3 would be implemented by this proposed rule. It would exempt vessels participating in a salmon bycatch reduction ICA from the BSAI salmon savings area closures. It is expected to reduce salmon bycatch in the BSAI pollock fisheries by penalizing participants that exhibit high salmon bycatch rates and rewarding participants that exhibit low salmon bycatch rates. Vessels participating in a salmon bycatch reduction ICA would be subject to a dynamic system of rolling ''hot spot'' closures dictated by the ICA and designed to reduce salmon bycatch. This alternative would likely reduce operational costs, improve vessel safety, and improve product quality. Alternative 3 also has the potential to reduce salmon bycatch more than the status quo management measures. If that potential is realized, Alternative 3 would reduce foregone value of salmon bycatch and increase the overall benefits of bycatch reduction. Alternative 3 also provides some mitigation possibilities for western Alaska subsistence salmon user groups by including them as parties to the ICA and enabling them to enforce compliance with the ICA's salmon bycatch reduction measures in Bering Sea pollock fisheries.

Alternative 3 would reduce management and enforcement costs for government agencies by transferring much of that cost to the fishing industry. The industry has volunteered to bear this cost in hopes of reducing operational costs associated with the status quo while at the same time attempting to reduce salmon bycatch. If bycatch is not reduced under Alternative 3, additional restrictions on the fleet could result.

This proposed rule contains collection-of-information requirements subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval under OMB control number 0648–0401. Public reporting burden is estimated per response to average: 40 hours for salmon bycatch reduction inter-cooperative agreement (ICA); 15 minutes for renewal of ICA; 28 hours for preliminary annual report; 12 hours for final annual report; 4 hours for ICA appeal.

Reporting burden includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed , and completing and reviewing the collection of information.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS (see **ADDRESSES**) and e-mail to *David_Rostker@omb.eop.gov*, or fax to (202) 395–7285.

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

The analysis did not reveal any Federal rules that duplicate, overlap, or conflict with the proposed action.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: April 11, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator For Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is proposed to be amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*; 1540(f); 1801 *et seq.*; 1851 note; 3631 *et seq.*

2. In § 679.2, the definition of ''Salmon bycatch reduction inter-cooperative agreement'' is added in alphabetical order to read as follows:

§ 679.2 Definitions.

* * * * *

Salmon bycatch reduction inter-cooperative agreement (ICA) is a voluntary chum and Chinook salmon catch avoidance agreement, as described at § 679.21(g) and approved by NMFS, for directed pollock fisheries in the Bering Sea subarea.

* * * * *

3. In § 679.7, paragraphs (d)(9) and (d)(10) are proposed to be revised to read as follows:

§ 679.7 Prohibitions.

* * * * *

(d) * * *

(9) For the operator of an eligible vessel, use trawl gear to harvest pollock CDQ in the Chinook Salmon Savings Area between January 1 and April 15, and between September 1 and December 31, after the CDQ group's Chinook salmon PSQ is attained, unless the vessel is participating in a salmon bycatch reduction ICA under § 679.21(e)(7)(ix).

(10) For the operator of an eligible vessel, use trawl gear to harvest pollock CDQ in the Chum Salmon Savings Area between September 1 and October 14 after the CDQ group's non-Chinook salmon PSQ is attained, unless the vessel is participating in a salmon bycatch reduction ICA under § 679.21(e)(7)(ix).

* * * * *

4. In § 679.21, paragraph (e)(7)(vii) is revised and paragraphs (e)(7)(ix) and (g) are added to read as follows:

§ 679.21 Prohibited species bycatch management.

* * * * *

(e) * * *

(7) * * *

(vii) *Chum salmon.* If the Regional Administrator determines that 42,000 non-Chinook salmon have been caught by vessels using trawl gear during August 15 through October 14 in the CVOA, defined under § 679.22(a)(5) and in Figure 2 to this part, NMFS will prohibit directed fishing for pollock for the remainder of the period September 1 through October 14 in the Chum Salmon Savings Area as defined in Figure 9 to this part.

* * * * *

(ix) *Exemptions.*

(A) Trawl vessels participating in directed fishing for pollock and operating under a salmon bycatch reduction ICA approved by NMFS are

exempt from closures in the Chum Salmon Savings Area described at § 679.21(e)(7)(vii). See also § 679.22(a)(10).

(B) Trawl vessels participating in directed fishing for pollock and operating under a salmon bycatch reduction ICA approved by NMFS are exempt from closures in area 2 of the Chinook Salmon Savings Area described at § 679.21(e)(7)(viii).

* * * * *

(g) *Requirements for vessels participating in a salmon bycatch reduction ICA.*

(1) *Who must file the salmon bycatch reduction ICA?* The representative for the salmon bycatch reduction ICA identified at (5)(v) of this paragraph must file a copy of the initial ICA and any amended salmon bycatch reduction ICA with NMFS.

(2) *With whom must the initial salmon bycatch reduction ICA and an amended salmon bycatch reduction ICA be filed?* The ICA representative must send a signed copy of the initial salmon bycatch reduction ICA and any amended salmon bycatch reduction ICA to the NMFS Alaska Region. The mailing address for the Regional Administrator, NMFS Alaska Region is P.O. Box 21668, Juneau, AK 99802. The street address for courier delivery is 709 West 9th St., Suite 401, Juneau, AK 99801.

(3) *What is the deadline for filing?* In order for any ICA participant to be exempt from salmon savings area closures as described at § 679.21(e)(7)(ix)(A), § 679.21(e)(7)(ix)(B) and § 679.22(a)(10), the salmon bycatch reduction ICA must be filed in compliance with the requirements of this section, and approved by NMFS. The initial salmon bycatch reduction ICA must be received by NMFS by December 1, 2007, for the 2008 fishing year. Exemptions from salmon savings area closures will expire upon termination of the initial ICA, expiration of the initial ICA, or if superseded by a NMFS-approved amended salmon bycatch reduction ICA.

(4) *How is the initial and an amended salmon bycatch reduction ICA approved by NMFS?* NMFS will approve the initial or an amended salmon bycatch reduction ICA if it meets all the requirements specified in paragraph (g)(5) of this section. If NMFS disapproves a salmon bycatch reduction ICA, the representative identified at (5)(v) of this section may resubmit a revised salmon bycatch reduction ICA or file an administrative appeal as set forth under the administrative appeals procedures described at § 679.43.

(5) *What are the minimum information requirements for the salmon bycatch reduction ICA?* The salmon bycatch ICA must include the following provisions:

(i) The names of the AFA cooperatives, CDQ groups, and third party groups that are parties to the ICA. The ICA must identify at least one third party group. Third party groups include any organizations representing western Alaskans who depend on Chinook and chum salmon and have an interest in salmon bycatch reduction but do not directly fish in a groundfish fishery. The ICA must identify one entity retained to facilitate vessel bycatch avoidance behavior and information sharing. Collectively, these groups are known as parties to the ICA. Parties to the ICA must agree to comply with all provisions of the ICA;

(ii) The names, Federal fisheries permit numbers, and USCG vessel identification numbers of vessels subject to the salmon bycatch reduction ICA;

(iii) Provisions that dictate salmon bycatch avoidance behaviors for vessel operators subject to the ICA, including:

(A) ''A'' season salmon bycatch management.

(*1*) Initial base rate calculation for Chinook salmon. The initial ''A'' season Chinook base rate shall be calculated by dividing the total number of Chinook taken incidentally in the ''A'' season prior year by the total number of metric tons of ''A'' season pollock catch during the prior year, except that if the initial ''A'' season Chinook base rate for any given year is less than or equal to .04 Chinook per metric ton of pollock, the initial base rate shall be .04 Chinook per metric ton, and if the initial base rate for any given year is equal to or greater than .06 Chinook per metric ton of pollock, the initial base rate shall be .06 Chinook per metric ton. Base rate calculations shall include Chinook salmon and pollock caught in both the CDQ and non-CDQ pollock directed fisheries.

(*2*) Inseason adjustments to the Chinook salmon base rate calculation. On February 14 of each year, the ''A'' season Chinook base rate shall be recalculated. The recalculated base rate shall be the Chinook bycatch rate for the current year, calculated by dividing the total number of Chinook salmon taken incidentally in the current ''A'' season by the total number of metric tons of ''A'' season pollock catch during the current season. The recalculated base rate shall be used to determine bycatch avoidance areas.

(*3*) ICA salmon savings area notices. On January 30 of each year and each Thursday and Monday thereafter for the duration of the pollock ''A'' season, the non-party entity retained to facilitate vessel bycatch avoidance behavior and information sharing identified in paragraph (g)(6)(i) of this section must provide notice to the parties to the salmon bycatch reduction ICA and NMFS identifying one or more areas designated as ''ICA Chinook Savings Areas'' by a series of latitude and longitude coordinates. The Thursday notice of ICA Chinook savings area designations must be effective from 6 pm Alaska local time the following Friday through 6 pm Alaska local time the following Tuesday. The Monday notice must be effective from 6 pm Alaska local time the following Tuesday through 6 pm Alaska local time the following Friday. For any ICA salmon savings area notice, the maximum total area closed must be at least 1000 square miles.

(*4*) Fishing restrictions for vessels assigned to Tiers as described at paragraph (g)(6)(iii)(C) of this section. ICA Chinook savings area closures announced on Thursdays must be closed to directed fishing for pollock, including pollock CDQ, by vessels assigned to Tier 3 for seven days. ICA Chinook savings area closures announced on Thursdays must be closed to vessels assigned to Tier 2 through 6 pm Alaska local time on the following Tuesday. Vessels assigned to Tier 1 may operate in any area designated as an ICA Chinook savings area.

(B) ''B'' season salmon bycatch management.

(*1*) ''B'' season Chinook salmon. For the ''B'' season of the 2008 fishing year, the Chinook salmon base rate shall be .05 Chinook salmon per metric ton of pollock. For the ''B'' season of the 2009 fishing year and each ''B'' season thereafter, the base rate shall be based on the Chinook salmon bycatch during a representative period of the prior year's ''B'' season. The recalculated base rate shall be used to determine bycatch avoidance areas. Base rate calculations shall include Chinook salmon and pollock caught in both the CDQ and non-CDQ pollock directed fisheries.

(*2*) Non-Chinook salmon. The initial ''B'' season non-Chinook salmon base rate shall be 0.19 non-Chinook salmon per metric ton of pollock.

(*3*) Inseason adjustments to the non-Chinook base rate calculation. Beginning July 1 of each fishing year, and on each Thursday during ''B'' season, the ''B'' season non-Chinook base rate shall be recalculated. The recalculated non-Chinook base rate shall be the three week rolling average of the ''B'' season non-Chinook bycatch rate for the current year. The recalculated

base rate shall be used to determine bycatch avoidance areas.

(*4*) ICA salmon savings area notices. On each Thursday and Monday after June 10 of each year for the duration of the pollock ''B'' season, the non-party entity retained to facilitate vessel bycatch avoidance behavior and information sharing identified in paragraph (g)(6)(i) of this section must provide notice to the parties to the salmon bycatch reduction ICA and NMFS identifying one or more areas designated as ''ICA Chinook Savings Areas'' and/or ''ICA Chum Savings Areas'' by a series of latitude and longitude coordinates. The Thursday notice of ICA Chinook savings area designations must be effective from 6 pm Alaska local time the following Friday through 6 pm Alaska local time the following Tuesday. The Monday notice must be effective from 6 pm Alaska local time the following Tuesday through 6 pm Alaska local time the following Friday. For any ICA salmon savings area notice, the maximum total area closed must be at least 3000 square miles for ICA chum savings area closures, and 500 square miles for ICA Chinook savings area closures.

(*5*) Fishing restrictions for vessels assigned to Tiers as described at paragraph (g)(6)(iii)(C) of this section. ICA chum savings area closures announced on Thursdays must be closed to directed fishing for pollock, including pollock CDQ, by vessels assigned to Tier 3 for seven days. ICA chum savings area closures announced on Thursdays must be closed to vessels assigned to Tier 2 through 6 pm Alaska local time on the following Tuesday. Vessels assigned to Tier 1 may operate in any area designated as an ICA chum savings area. ICA Chinook savings areas must be closed to fishing by all vessels identified at paragraph (g)(6)(iii)(C) of this section.

(C) *Cooperative tier assignments.* Initial and subsequent base rate calculations must be based on each cooperative's pollock catch for the prior two weeks and the associated bycatch of Chinook or non-Chinook salmon taken by its members. Base rate calculations shall include salmon bycatch and pollock caught in both the CDQ and non-CDQ pollock directed fisheries. Coops with salmon bycatch rates of less than 75 percent of the base rate shall be assigned to Tier 1. Coops with salmon bycatch rates of equal to or greater than 75 percent but equal to or less than 125 percent of the base rate shall be assigned to Tier 2. Coops with salmon bycatch rates of greater than 125 percent of the base rate shall be assigned to Tier 3. Bycatch rates for Chinook salmon must be calculated separately from non-Chinook salmon, and cooperatives must be assigned to tiers separately for Chinook and non-Chinook salmon bycatch.

(iv) Internal monitoring and enforcement provisions to ensure compliance of fishing activities with the provisions of the ICA. The ICA must include provisions allowing any party of the ICA to bring civil suit or initiate a binding arbitration action against another for breach of the ICA. The ICA must include minimum annual uniform assessments for any violation of savings area closures of $10,000 for the first offense, $15,000 for the second offense, and $20,000 for each offense thereafter;

(v) The name, phone number, and business address of the person who will annually file ICA with NMFS;

(vi) Provisions requiring the parties to conduct an annual compliance audit, and to cooperate fully in such audit, including providing information required by the auditor. The compliance audit must be conducted by a non-party entity, and each party must have an opportunity to participate in selecting the non-party entity. If the non-party entity hired to conduct a compliance audit discovers a previously undiscovered failure to comply with the terms of the ICA, the non-party entity must notify all parties to the ICA of the failure to comply and must simultaneously distribute to all parties of the ICA information used to determine the failure to comply occurred and must include such notice(s) in the compliance report described in § 679.61(f)(2)(vii).

(vii) Provisions requiring data dissemination in certain circumstances. If the entity retained to facilitate vessel bycatch avoidance behavior described at § 679.61(g)(6)(i) determines that an apparent violation of an ICA savings are closure has occurred, that entity must promptly notify the Board of Directors of the cooperative to which the vessel involved belongs. If this Board of Directors fails to assess a minimum uniform assessment within 60 days of receiving the notice, the information used by the entity retained to facilitate vessel bycatch avoidance behavior to determine if an apparent violation was committed must be disseminated to all parties to the ICA.

* * * * *

5. In § 679.22, paragraph (a)(10) is revised to read as follows:

§ 679.22 Closures.

* * * * *

(a) * * *

(10) *Chum Salmon Savings Area.* Directed fishing for pollock by vessels using trawl gear is prohibited from August 1 through August 31 in the Chum Salmon Savings Area defined at Figure 9 to this part (see also § 679.21(e)(7)(vii)). Vessels using trawl gear participating in directed fishing for pollock, including pollock CDQ, and operating under a salmon bycatch reduction ICA are exempt from closures in the Chum Salmon Savings Area. See also § 679.21(e)(7)(vii).

* * * * *

6. In § 679.61, paragraph (f)(2)(vii) is added to read as follows:

§ 679.61 Formation and operation of fishery cooperatives.

* * * * *

(f) * * *

(2) * * *

(vii) The annual report must indicate the number of salmon taken by species and season, estimate number of salmon avoided as demonstrated by the movement of fishing effort away from salmon savings areas, include the results of the compliance audit described at § 679.21(g)(6)(vi), and list of each vessels number of appearances on the weekly dirty 20 lists for both salmon species.

* * * * *

[FR Doc. E7–7380 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 72, No. 74
Wednesday, April 18, 2007

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Northern Research Station's Outreach Opportunity Questionnaire

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the Northern Research Station's (NRS) Outreach Opportunity Questionnaire.

DATES: Comments must be received in writing on or before June 18, 2007 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to the Northern Research Station, Attention: Judy Terrell, Forest Service, USDA, 11 Campus Boulevard, Suite 200, Newtown Square, PA 19073.

Comments also may be submitted via facsimile to 610–557–4095 or by e-mail to: *jterrell@fs.fed.us.*

The public may inspect comments received at USDA Forest Service, 11 Campus Boulevard, Suite 200, Newtown Square, PA 19073 during normal business hours. Visitors are encouraged to call ahead to 610–557–4257 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Judy Terrell, Administrative Services, 610–557–4257. Individuals who use TDD may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Northern Research Station's Outreach Opportunity Questionnaire.

OMB Number: 0596–NEW.

Type of Request: New.

Abstract: This information collection is proposed in order to gather information from students attending local college and university career fairs regarding the effectiveness of the information provided by Forest Service personnel on career opportunities in the Forest Service. The information collection is necessary to evaluate and determine the effectiveness of the Forest Service Northern Research Station's (NRS) Civil Rights Outreach Program.

Forest Service Civil Rights personnel will use a postcard size form to collect evaluation information from students regarding presentations at career day events at colleges and universities. Data received will appear in reports provided to the Department of Agriculture, senior Forest Service officials, the NRS Director, and the NRS Civil Rights Diversity Committee. This information is a vital component in the analysis of Agency outreach efforts.

Estimate of Annual Burden: 10 minutes (.17 hours).

Type of Respondents: University/College students.

Estimated Annual Number of Respondents: 500.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 85 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: April 13, 2007.

Ann M. Bartuska,

Deputy Chief, Research and Development.

[FR Doc. E7–7372 Filed 4–17–07; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

National Urban and Community Forestry Advisory Council

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Urban and Community Forestry Advisory Council will meet in Biloxi, Mississippi, June 5–7, 2007. The purpose of the meeting is to discuss emerging issues in urban and community forestry.

DATES: The meeting will be held on June 5–7, 2007.

ADDRESSES: The business meetings on June 5 and 7 will be held at the Quality Inn, 2416 Beach Blvd., Biloxi, MS. A *Catastrophic Storms and Urban Forests* public listening session will be held on June 6 at the Mississippi Coast Coliseum and Convention Center, 2350 Beach Blvd., Biloxi, MS. Written comments concerning this meeting should be addressed to Suzanne M. del Villar, Executive Assistant, National Urban and Community Forestry Advisory Council, P.O. Box 1003, Sugarloaf, CA 92386–1003. Comments may also be sent via e-mail to *sdelvillar@fs.fed.us,* or via facsimile to (909) 585–9527.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at USDA Forest Service, Urban and Community Forestry, 201 14th Street, SW., 1 Central Yates Building, Washington, DC. Visitors are encouraged to call ahead to 202–205–1057 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Suzanne M. del Villar, Urban and Community Forestry Staff, (909) 585–9268, or via e-mail at *sdelvillar@fs.fed.us,*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Council will be hosting a groundbreaking public listening session on *Catastrophic Storms and Urban Forests* on June 6, 2007, at the Mississippi Coast Coliseum and Convention Center, 2350 Beach Blvd., Biloxi, MS. There are several ways for the public to offer their testimony as explained on the Council's Web site at *http://www.treelink.org/nucfac.* Participants may give an on-site presentation, Web cast, written form, fax or e-mail. All testimony will be recorded, compiled, and tabulated into a final report to the Secretary of Agriculture.

Dated: April 11, 2007.

Robin L. Thompson,

Associate Deputy chief, State & Private Forestry.

[FR Doc. 07–1928 Filed 4–17–07; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Announcement of Rural Cooperative Development Grant Application Deadlines and Funding Levels

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice of solicitation of applications.

SUMMARY: Rural Business-Cooperative Service programs are administered through USDA Rural Development. USDA Rural Development announces the availability of approximately $3.5 million in competitive grant funds for the fiscal year (FY) 2007 Rural Cooperative Development Grant (RCDG) Program. The intended effect of this notice is to solicit applications for FY 2007 and award grants on or before September 14, 2007. The maximum award per grant is $200,000 and matching funds are required.

DATES: Applications for grants must be submitted on paper or electronically according to the following deadlines:

Paper copies must be postmarked and mailed, shipped, or sent overnight no later than June 8, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

Electronic copies must be received by June 8, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

ADDRESSES: Application materials for a RCDG may be obtained at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm* or by contacting the applicant's USDA Rural Development State Office at (202) 720–4323 and pressing ''1''.

Submit completed paper applications for a grant to Cooperative Programs, Attn: RCDG Program, 1400 Independence Avenue, SW., Mail Stop 3250, Room 4016-South, Washington, DC 20250–3250. The phone number that should be used for courier delivery is (202) 720–7558.

Submit electronic grant applications at *http://www.grants.gov,* following the instructions found on this Web site.

FOR FURTHER INFORMATION CONTACT: Visit the program Web site at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm* for application assistance or contact your USDA Rural Development State Office at (202) 720–4323 and press ''1'', or select the Contacts link at the above Web site. Applicants are encouraged to contact their State Offices well in advance of the deadline to discuss their projects and ask any questions about the application process.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Business-Cooperative Service (RBS).

Funding Opportunity Title: Rural Cooperative Development Grant.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance Number: 10.771.

Dates: Application Deadline: Completed applications for grants may be submitted on paper or electronically according to the following deadlines:

Paper copies must be postmarked and mailed, shipped, or sent overnight no later than June 8, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

Electronic copies must be received by June 8, 2007, to be eligible for FY 2007 grant funding. Late applications are not eligible for FY 2007 grant funding.

I. Funding Opportunity Description

RCDGs are authorized by section 310B(e) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(e)). Regulations are contained in 7 CFR part 4284, subparts A and F. The primary objective of the RCDG program is to improve the economic condition of rural areas through cooperative development. Grant funds are provided for the establishment and operation of Centers that have the expertise or who can contract out for the expertise to assist individuals or entities in the startup, expansion or operational improvement of cooperative businesses. The program is administered through USDA Rural Development State Offices.

Definitions

The definitions published at 7 CFR 4284.3 and 4284.504 are incorporated by reference.

II. Award Information

Type of Award: Grant.

Fiscal Year Funds: FY 2007.

Approximate Total Funding: $3.5 million.

Approximate Number of Awards: 18.

Approximate Average Award: $200,000.

Floor of Award Range: None.

Ceiling of Award Range: $200,000.

Anticipated Award Date: September 14, 2007.

Budget Period Length: 12 months.

Project Period Length: 12 months.

III. Eligibility Information

A. Eligible Applicants

Grants may be made to nonprofit corporations and institutions of higher education. Grants may not be made to public bodies.

B. Cost Sharing or Matching

Matching funds are required. Applicants must verify in their applications that all matching funds are available for the time period of the grant. The matching fund requirement is 25 percent of the total project cost (5 percent in the case of 1994 Institutions). Unless provided by other authorizing legislation, other Federal grant funds cannot be used as matching funds. However, matching funds may include loan proceeds from Federal sources. Matching funds must be spent in advance or as a pro-rata portion of grant funds being expended. All of the matching funds must be provided by either the applicant or a third party in the form of cash or in-kind contributions. All of the matching funds must be spent on eligible expenses and must be from eligible sources. The Center must be able to document and verify the number of hours worked and the value associated with the in-kind contribution. Additionally, if the in-kind contributions are from board members for their time, travel, incidentals, etc., the Center must have established written policies explaining how these costs are normally reimbursed, including rates. Otherwise, the in-kind contributions will not be considered eligible expenses and may cause the application to be determined ineligible for funding. In-kind contributions provided by individuals, businesses, or cooperatives who are being assisted by the Center can not be

provided for the benefit of their own projects as USDA Rural Development considers this to be a conflict of interest or the appearance of a conflict of interest.

C. Other Eligibility Requirements

Grant Period Eligibility: Applications should have a timeframe of no more than 365 days with the time period beginning no earlier than October 1, 2007 and no later than January 1, 2008. Projects must be completed within the 1-year timeframe. The Agency will not approve requests to extend the grant period.

Completeness Eligibility: Applications without sufficient information to determine eligibility and scoring will be considered ineligible. Applications that are non-responsive to this notice will be considered ineligible.

Activity Eligibility: Applications must propose the development or continuation of the cooperative development center concept or they will not be considered for funding. Additionally, applications that focus assistance to only one cooperative will not be considered for funding. Applications requesting more than the maximum grant amount will not be considered for funding. Applications that have ineligible costs that equal more than 10 percent of the total project costs will be determined ineligible, and not be considered for funding. If an application has ineligible costs of 10 percent or less of total project costs and is selected for funding, the applicant must remove all ineligible costs from the budget and replace them with eligible activities or the amount of the grant award will be reduced accordingly.

IV. Application and Submission Information

A. Address To Request Application Package

The application package for applying on paper for this funding opportunity can be obtained at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm.* Alternatively, applicants may contact their USDA Rural Development State Office at (202) 720–4323 and press ''1''. For electronic applications, applicants must visit *http://www.grants.gov* and follow the instructions.

B. Content and Form of Submission

Applications must be submitted on paper or electronically. An application guide may be viewed at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm*. It is recommended that applicants use the template provided on the Web site. The template can be filled out electronically and printed out for submission with the required forms for paper submission or it can be filled out electronically and submitted as an attachment through *http://www.grants.gov.*

If an application is submitted on paper, one signed original of the complete application must be submitted in the following format:

- Font size: 12 point unreduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: 1 inch on the top, bottom, left, and right.
- Printed on only one side of each page.
- Held together only by rubber bands or metal or plastic clips; not bound in any other way.
- Language: English, avoid jargon.

The submission must include all pages of the application. It is recommended that the application be in black and white, not color. Those evaluating the application will only receive black and white images.

If the application is submitted electronically, the applicant must follow the instructions given at *http://www.grants.gov.* Applicants are advised to visit the site well in advance of the application deadline if they plan to apply electronically to ensure they have obtained the proper authentication and have sufficient computer resources to complete the application.

Applicants must complete and submit the following elements. The Agency will screen all applications for eligibility and to determine whether the application is complete and sufficiently responsive to the requirements set forth in this notice to allow for an informed review. Information submitted as part of the application will be protected to the extent permitted by law.

1. Form SF–424, ''Application for Federal Assistance.'' The form must be completed, signed and submitted as part of the application package.

Please note that applicants are required to have a DUNS number to apply for a grant from USDA Rural Development. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. There is no charge. To obtain a DUNS number, access *http://www.dnb.com/us/* or call 866–705–5711. For more information, see the RCDG Web site at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm* or contact the applicant's USDA Rural Development State Office at (202) 720–4323 and press ''1''.

2. Form SF–424A, ''Budget Information—Non-Construction Programs.''

This form must be completed and submitted as part of the application package.

3. Form SF–424B, ''Assurances—Non-Construction Programs.'' This form must be completed, signed, and submitted as part of the application package.

4. Survey on Ensuring Equal Opportunity for Applicants. The Agency is required to make this survey available to all nonprofit applicants. Submitting this form is voluntary.

5. Title Page. The Title Page, not to exceed one page, should include the title of the project as well as any other relevant identifying information.

6. Table of Contents. For ease of locating information, each proposal must contain a detailed Table of Contents (TOC) immediately following the Title Page. The TOC should include page numbers for each component of the application.

7. Executive Summary. A summary of the proposal, not to exceed two pages, must briefly describe the Center, including project goals and tasks to be accomplished, the amount requested, how the work will be performed (e.g., Center staff, consultants, or contractors) and the percentage of work that will be performed among the parties.

8. Eligibility. The applicant must describe, not to exceed two pages, how it meets the applicant, matching, grant period and activity eligibility requirements.

9. Proposal Narrative. The proposal narrative is limited to a total of 40 pages.

i. Project Title. The title of the proposed project must be brief, not to exceed 75 characters, yet describe the essentials of the project. If a title page was included under number 5 above, it is not necessary to include an additional title page under this section.

ii. Information Sheet. A separate one-page information sheet listing each of the evaluation criteria referenced in the RFP, followed by the page numbers of all relevant material and documentation contained in the proposal that address or support the criteria. If the evaluation criteria are listed on the Table of Contents and specifically and individually addressed in narrative form, then it is not necessary to include an information sheet under this section.

iii. Goals of the Project. The applicant must include the following statements in this section of the narrative to demonstrate that the Center is following these statutory requirements:

1. A statement that substantiates that the Center will effectively serve rural areas in the United States;

2. A statement that the primary objective of the Center will be to

improve the economic condition of rural areas through cooperative development;

3. A description of the contributions that the proposed activities are likely to make to the improvement of the economic conditions of the rural areas for which the Center will provide services; and

4. A statement that the Center, in carrying out its activities, will seek, where appropriate, the advice, participation, expertise, and assistance of representatives of business, industry, educational institutions, the Federal government, and State and local governments.

iv. Work Plan. Please see section V. A. 8. for specific requirements on the work plan and budget. The work plan and budget should be presented under proposal evaluation criterion number 8. It is not necessary to include the work plan and budget under this section.

v. Performance Evaluation Criteria. The Agency has established annual performance measures to evaluate the RCDG program. Applicants must provide estimates on the following performance measures.

- Number of groups who are not legal entities assisted.
- Number of businesses that are not cooperatives assisted.
- Number of cooperatives assisted.
- Number of businesses incorporated that are not cooperatives.
- Number of cooperatives incorporated.
- Total number of jobs created as a result of assistance.
- Total number of jobs saved as a result of assistance.
- Number of jobs created for the Center as a result of RCDG funding.
- Number of jobs saved for the Center as a result of RCDG funding.

It is permissible to have a zero in a performance element. When calculating jobs created, estimates should be based upon actual jobs to be created by the Center as a result of the RCDG funding or actual jobs to be created by businesses or cooperatives as a result of assistance from the Center. When calculating jobs saved, estimates should be based only on actual jobs that would have been lost if the Center did not receive RCDG funding or actual jobs that would have been lost without assistance from the Center. If the application is selected for funding, the applicant will be required to report actual numbers for these performance elements on a semi-annual basis and in the final performance report. Additional information on post-award requirements can be found in Section VI. Applicants may also suggest additional performance criteria in the event the proposal receives grant funding. The criteria are not binding on USDA, but should be specific, measurable performance criteria. The inclusion of additional performance criteria beyond the nine listed above is voluntary.

vi. Undertakings. The applicant must include the following statements in this section of the narrative and expressly undertake to do them.

1. Take all practicable steps to develop continuing sources of financial support for the Center, particularly from sources in the private sectors;

2. Make arrangements for the Center's activities to be monitored and evaluated; and

3. Provide an accounting for the money received by the grantee in accordance with 7 CFR part 4284, subpart F.

vii. Delivery of Cooperative development assistance. Please see section V. A. 7. for specific requirements on delivery of cooperative development assistance. Delivery should be presented under proposal evaluation criterion number 7. It is not necessary to include discussion on delivery of cooperative development assistance under this section.

viii. Qualifications of Personnel. Please see section V. A. 9. for specific requirements on qualifications of personnel. Qualifications of personnel should be presented under proposal evaluation criterion number 9. It is not necessary to include discussion on qualifications of personnel under this section.

ix. Support and commitments. Please see section V. A. 10. for specific requirements on support and commitments. Support and commitments should be presented under proposal evaluation criterion number 10. It is not necessary to include discussion on support and commitments under this section.

x. Future Support. Please see section V. A. 11. for specific requirements on future support. Future support should be presented under proposal evaluation criterion number 11. It is not necessary to include discussion on future support under this section.

xi. Proposal Evaluation Criteria. Each of the evaluation criteria referenced in this funding announcement must be specifically and individually addressed in narrative form. Applications that do not address all of the proposal evaluation criteria will be considered ineligible. See Section V. A. for a description of the Proposal Evaluation Criteria.

10. Certification of Judgment Owed to the United States. Applicants must certify that the United States has not obtained a judgment against them. No grant funds shall be used to pay a judgment obtained by the United States. It is suggested that applicants use the following language for the certification. ''[INSERT NAME OF APPLICANT] certifies that the United States has not obtained a judgment against it.'' A separate signature is not required.

11. Certification of Matching Funds. Applicants must certify that matching funds will be available at the same time grant funds are anticipated to be spent and that matching funds will be spent in advance of grant funding, such that for every dollar of the total project cost, not less than the required amount of matching funds will have been expended prior to submitting the request for reimbursement. Please note that this certification is a separate requirement from the Verification of Matching Funds requirement. Applicants should include a statement for this section that reads as follows: ''[INSERT NAME OF APPLICANT] certifies that matching funds will be available at the same time grant funds are anticipated to be spent and that matching funds will be spent in advance of grant funding, such that for every dollar of the total project cost, at least 25 cents (5 cents for 1994 Institutions) of matching funds will have been expended prior to submitting the request for reimbursement.'' A separate signature is not required.

12. Verification of Matching Funds. Applicants must provide documentation of all proposed matching funds, both cash and in-kind. The documentation must be included in Appendix A and will not count towards the 40-page limitation.

If matching funds are to be provided by the applicant in cash, there must be a statement that cash will be available, the amount of the cash, and the source of the cash. Applicants should note that only goods or services for which no expenditure is made can be considered in-kind. If the applicant is paying for goods and services as part of the matching funds contribution, the expenditure is considered a cash match, and should be verified as such. If the matching funds are to be provided by a third party in cash, the application must include a signed letter from that third party verifying how much cash will be donated and when it will be donated. Verification for funds donated outside the proposed time period of the grant will not be accepted.

If the matching funds are to be provided by a third party in-kind donation, the application must include a signed letter from the third party

verifying the goods or services to be donated, when the goods and services will be donated, and the value of the goods or services. Verification for in-kind contributions donated outside the proposed time period of the grant will not be accepted. Verification for in-kind contributions that are over-valued will not be accepted. The valuation process for in-kind funds does not need to be included in the application. However, the applicant must be able to demonstrate how the valuation was derived at the time of notification of tentative selection for the grant award. If the applicant cannot satisfactorily demonstrate how the valuation was determined, the grant award may be withdrawn or the amount of the grant may be reduced.

If matching funds are in cash, they must be spent on goods and services that are eligible expenditures for this grant program. If matching funds are in-kind contributions, the donated goods or services must be considered eligible expenditures for this grant program as well as be used for eligible purposes. The matching funds must be spent or donated during the grant period and the funds must be expended in advance or as a pro-rata portion of grant funds being expended. Examples of unacceptable matching funds are in-kind contributions from individuals, businesses, or cooperatives being assisted by the Center to benefit their own project, donations of fixed equipment and buildings, and the preparation of the RCDG application package.

Expected program income may not be used to fulfill the matching funds requirement at the time of application. If program income is earned during the time period of the grant, it is subject to the requirements of 7 CFR part 3015, subpart F and 7 CFR part 3019.24 and any provisions in the Grant Agreement.

C. Submission Dates and Times

Application Deadline Date: June 8, 2007

Explanation of Deadlines: Paper applications must be postmarked by the deadline date (see Section IV.F for the address). Electronic applications must be received by *http://www.grants.gov* by the deadline date. If the application does not meet the deadline above, it will not be considered for funding. The applicant will be notified if the application does not meet the submission requirements. The applicant will also be notified by mail or by e-mail if the application is received on time.

D. Intergovernmental Review of Applications

Executive Order 12372, Intergovernmental review of Federal programs, applies to this program. This EO requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many states have established a Single Point of Contact (SPOC) to facilitate this consultation. For a list of states that maintain an SPOC, please see the White House Web site: *http://www.whitehouse.gov/omb/grants/spoc.html.* If an applicant's state has an SPOC, the applicant may submit a copy the application directly for review. Any comments obtained through the SPOC must be provided to USDA Rural Development for consideration as part of the application. If the applicant's state has not established an SPOC, or the applicant does not want to submit a copy of the application, USDA Rural Development will submit the application to the SPOC or other appropriate agency or agencies.

Applicants are also encouraged to contact the USDA Rural Development State Office for assistance and questions on this process. The USDA Rural Development State Office can be reached at (202) 720–4323 and selecting option ''1'' or by viewing the following Web site: *http://www.rurdev.usda/.*

E. Funding Restrictions

Funding restrictions apply to both grant funds and matching funds. Grant funds may be used to pay up to 75 percent (95 percent where the grantee is a 1994 Institution) of the total project cost.

1. Grant funds and matching funds may be used for, but are not limited to, providing the following to individuals, cooperatives, small businesses and other similar entities in rural areas served by the Center:

i. Applied research, feasibility, environmental and other studies that may be useful for the purpose of cooperative development.

ii. Collection, interpretation and dissemination of principles, facts, technical knowledge, or other information for the purpose of cooperative development.

iii. Training and instruction for the purpose of cooperative development.

iv. Loans and grants for the purpose of cooperative development in accordance with this notice and applicable regulations.

v. Technical assistance, research services and advisory services for the purpose of cooperative development.

2. No funds made available under this solicitation shall be used for any of the following activities:

i. To duplicate current services or replace or substitute support previously provided. If the current service is inadequate, however, grant funds may be used to expand the level of effort or services beyond that which is currently being provided;

ii. To pay costs of preparing the application package for funding under this program;

iii. To pay costs of the project incurred prior to the date of grant approval;

iv. To fund political activities;

v. To pay for assistance to any private business enterprise that does not have at least 51 percent ownership by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence;

vi. To pay any judgment or debt owed to the United States;

vii. To plan, repair, rehabilitate, acquire, or construct a building or facility, including a processing facility;

viii. To purchase, rent, or install fixed equipment, including laboratory equipment or processing machinery;

ix. To pay for the repair of privately owned vehicles;

x. To fund research and development;

xi. To pay costs of the project where a conflict of interest exists; or

xii. To fund any activities prohibited by 7 CFR parts 3015 or 3019.

F. Other Submission Requirements

A paper application for a grant must be submitted to Cooperative Programs, Attn: RCDG Program, 1400 Independence Avenue, SW., Mail Stop 3250, Room 4016–South, Washington, DC 20250–3250. The phone number that should be used for courier delivery is (202) 720–7558. Electronically submitted applications must apply using the following internet address: *http://www.grants.gov.* Applications may not be submitted by electronic mail, facsimile, or by hand-delivery. Each application submission must contain all required documents in one envelope, if by mail or courier delivery service.

V. Application Review Information

A. Proposal Evaluation Criteria

All eligible and complete applications will be evaluated based on the following criteria. Evaluators will base scores only on the information provided or cross-referenced in each individual evaluation criterion. The maximum amount of points available is 65.

1. *Administrative capabilities.* (0–7 points) The application will be evaluated to determine whether the subject Center has a track record of administering a Nationally-coordinated, regional or State-wide operated project. Centers that have capable financial systems and audit controls, personnel and program administration performance measures and clear rules of governance will receive more points than those not evidencing this capacity. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates weakness in all areas of the criterion.

• 3–4 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.

• 5–6 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.

• 7 points will be awarded if the applicant demonstrates that the Center has a track record of administering project(s) and their financial systems and audit controls, personnel and program administration performance measures and clear rules of governance are outstanding and could not be improved.

2. *Technical assistance and other services.* (0–7 points) The Agency will evaluate the applicant's demonstrated expertise in providing technical assistance in rural areas. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates weakness in providing technical assistance in rural areas.

• 3–4 points will be awarded if the applicant demonstrates that their expertise in providing technical assistance in rural areas is adequate.

• 5–6 points will be awarded if the applicant demonstrates that their expertise in providing technical assistance in rural areas is above average.

• 7 points will be awarded if the applicant demonstrates that their expertise in providing technical assistance in rural areas is outstanding and could not be improved.

3. *Economic development.* (0–7 points) The Agency will evaluate the applicant's demonstrated ability to assist in the retention of businesses, facilitate the establishment of cooperatives and new cooperative approaches and generate employment opportunities that will improve the economic conditions of rural areas. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates weakness in all areas of the criterion.

• 3–4 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.

• 5–6 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.

• 7 points will be awarded if the applicant demonstrates outstanding ability to assist in improvements to the economic conditions of rural areas.

4. *Linkages.* (0–7 points) The Agency will evaluate the applicant's demonstrated ability to create horizontal linkages among businesses within and among various sectors in rural areas of the United States and vertical linkages to domestic and international markets. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates weakness in all areas of the criterion.

• 3–4 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.

• 5–6 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.

• 7 points will be awarded if the applicant demonstrates outstanding ability to create horizontal and vertical linkages.

5. *Commitment.* (0–7 points) The Agency will evaluate the applicant's commitment to providing technical assistance and other services to underserved and economically distressed areas in rural areas of the United States. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates weakness in all areas of the criterion.

• 3–4 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.

• 5–6 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.

• 7 points will be awarded if the applicant demonstrates outstanding commitment to underserved and economically distressed areas in rural areas.

6. *Matching Funds.* (3 or 5 points) All applicants must demonstrate matching funds equal to at least 25 percent (5 percent for 1994 Institutions) of total project costs. Applications exceeding these minimum commitment levels will receive more points. If the applicant provides eligible matching funds of 26 to 50 percent, 3 points will be awarded; or greater than 50 percent, 5 points will be awarded. If the applicant is a 1994 Institution and provides eligible matching funds of 6 to 20 percent, 3 points will be awarded; or greater than 20 percent, 5 points will be awarded.

7. *Delivery.* (0–5 points) The Agency will evaluate whether the Center has a track record of providing technical assistance in rural areas and accomplishing effective outcomes in cooperative development. The Center's potential for delivering effective cooperative development assistance, the expected effects of that assistance, the sustainability of cooperative organizations receiving the assistance, and the transferability of the Center's cooperative development strategy and focus to other States will also be assessed. Points will be awarded as follows:

• 0 points will be awarded if the applicant does not substantively address the criterion.

• 1–2 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.

• 3–4 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.

• 5 points will be awarded if the applicant demonstrates that all areas of the criterion are outstanding and could not be improved.

8. *Work Plan/Budget.* (0–5 points) The work plan will be reviewed for detailed actions and an accompanying timetable for implementing the proposal. Clear, logical, realistic and efficient plans will result in a higher score. Budgets will be reviewed for completeness and the quality of non-Federal funding commitments. Applicants must discuss the specific tasks (whether it be by type of service or specific project) to be completed using grant and matching funds. The work plan should show how customers will be identified, key personnel to be involved, and the evaluation methods to be used to determine the success of specific tasks and overall objectives of Center operations. The budget must present a breakdown of the estimated costs associated with cooperative development activities as well as the operation of the Center and allocate these costs to each of the tasks to be undertaken. Matching funds as well as grant funds must be accounted for in the

budget. Points will be awarded as follows:

- 0 points will be awarded if the applicant does not substantively address the criterion.
- 1–2 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.
- 3–4 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.
- 5 points will be awarded if the applicant demonstrates that all areas of the criterion are outstanding and could not be improved.

9. *Qualifications of those Performing the Tasks.* (0–5 points) The application will be evaluated to determine if the personnel expected to perform key center tasks have a track record of positive solutions for complex cooperative development or marketing problems, or a successful record of conducting accurate feasibility studies, business plans, marketing analysis, or other activities relevant to Cooperative development center success. The applicant must also identify whether the personnel expected to perform tasks are full/part-time Center employees or contract personnel. Points will be awarded as follows:

- 0 points will be awarded if the applicant does not substantively address the criterion.
- 1–2 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.
- 3–4 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.
- 5 points will be awarded if the applicant demonstrates that all areas of the criterion are outstanding and could not be improved.

10. *Local support.* (0–5 points) Applications will be reviewed for previous and expected local support for the Center, plans for coordinating with other developmental organizations in the proposed service area, and coordination with State and local institutions. Support documentation should include recognition of rural values that balance employment opportunities with environmental stewardship and other positive rural amenities. Centers that demonstrate strong support from potential beneficiaries and formal evidence of the Center's intent to coordinate with other developmental organizations will receive more points than those not evidencing such support and formal intent. Support should be discussed directly within the response to this criterion. The applicant may submit a maximum of 10 letters of support or intent to coordinate with the application. These letters should be included in Appendix B of the application and will not count against the 40-page limit for the narrative. Points will be awarded as follows:

- 0 points will be awarded if the applicant does not substantively address the criterion.
- 1–2 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.
- 3–4 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.
- 5 points will be awarded if the applicant demonstrates that all areas of the criterion are strong and the support from potential beneficiaries and formal evidence of the Center's intent to coordinate with other developmental organizations are outstanding and could not be improved.

11. *Future support.* (0–5 points) Applicants should describe their vision for Center operations in future years, including issues such as sources and uses of alternative funding; reliance on Federal, State, and local grants; and the use of in-house personnel for providing services versus contracting out for that expertise. To the extent possible, applicants should document future funding sources that will help achieve long-term sustainability of the Center. Applications that demonstrate their vision for funding center operations for future years, including diversification of funding sources and building in-house technical assistance capacity, will receive more points for this criterion. Points will be awarded as follows:

- 0 points will be awarded if the applicant does not substantively address the criterion.
- 1–2 points will be awarded if the applicant demonstrates that they meet part, but not all, of the criterion.
- 3–4 points will be awarded if the applicant demonstrates that all areas of the criterion are strong.
- 5 points will be awarded if the applicant demonstrates that all areas of the criterion are strong and their diversification of funding sources and ability to build in-house technical assistance capacity are outstanding and could not be improved.

B. Review and Selection Process

The Agency will screen all of the proposals to determine whether the application is eligible and sufficiently responsive to the requirements set forth in this notice to allow for an informed review.

The Agency will evaluate applications using a panel of qualified reviewers who will score the applications in accordance with the point allocation specified in this notice. Applications will be submitted to the Administrator in rank order, together with funding level recommendations.

C. Anticipated Announcement and Award Dates

Award Date: The announcement of award selections is expected to occur on or about September 14, 2007.

VI. Award Administration Information

A. Award Notices

Successful applicants will receive a notification of tentative selection for funding from USDA Rural Development. Applicants must comply with all applicable statutes and regulations before the grant award will be approved. Unsuccessful applicants will receive notification by mail.

B. Administrative and National Policy Requirements

7 CFR parts 3015, 3019, and 4284. To view these regulations, please see the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to grantees selected for this program:

- Grant Agreement.
- Letter of Conditions.
- Form RD 1940–1, ''Request for Obligation of Funds.''
- Form RD 1942–46, ''Letter of Intent to Meet Conditions.''
- Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions.''
- Form AD–1048, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions.''
- Form AD–1049, ''Certification Regarding Drug-Free Workplace Requirements (Grants).''
- Form RD 400–4, ''Assurance Agreement.''
- RD Instruction 1940–Q, Exhibit A–1, ''Certification for Contracts, Grants and Loans.''
- Form RD 2006–38, ''Civil Rights Impact Analysis.'' Prior to approval of all grants, a Civil Rights Impact Analysis will be conducted.

Additional information on these requirements can be found at *http://www.rurdev.usda.gov/rbs/coops/rcdg/rcdg.htm.*

Reporting Requirements: Grantees must provide USDA Rural Development with an original or electronic copy that includes all required signatures of the following reports. The reports should be submitted to the Agency contact listed

on the Grant Agreement and Letter of Conditions. Failure to submit satisfactory reports on time may result in suspension or termination of the grant.

1. Form SF–269 or SF–269A. A ''Financial Status Report'' listing expenditures according to agreed upon budget categories, on a semi-annual basis. Reporting periods end each March 31 and September 30. Reports are due 30 days after the reporting period ends.

2. Semi-annual performance reports that compare accomplishments to the objectives stated in the proposal. Identify all tasks completed to date and provide documentation supporting the reported results. If the original schedule provided in the work plan is not being met, the report should discuss the problems or delays that may affect completion of the project. Objectives for the next reporting period should be listed. Compliance with any special conditions on the use of award funds should be discussed. The report should also include a summary at the end of the report with the following elements to assist in documenting the annual performance goals of the RCDG program for Congress.

- Number of groups who are not legal entities assisted.
- Number of businesses that are not cooperatives assisted.
- Number of cooperatives assisted.
- Number of businesses incorporated that are not cooperatives.
- Number of cooperatives incorporated.
- Total number of jobs created as a result of assistance.
- Total number of jobs saved as a result of assistance.
- Number of jobs created for the Center as a result of RCDG funding.
- Number of jobs saved for the Center as a result of RCDG funding.

Reports are due as provided in paragraph 1 of this section. Supporting documentation must also be submitted for completed tasks. The supporting documentation for completed tasks includes, but is not limited to: feasibility studies, marketing plans, business plans, publication quality success stories, applied research reports, copies of surveys conducted, articles of incorporation and bylaws and an accounting of how outreach, training, and other funds were expended.

3. Final project performance reports. These reports shall include all of the requirements of the semi-annual performance reports and responses to the following:

i. What have been the most challenging or unexpected aspects of this program?

ii. What advice would the Grantee give to other organizations planning a similar program? These should include strengths and limitations of the program. If the Grantee had the opportunity, what would they have done differently?

iii. If an innovative approach was used successfully, the Grantee should describe their program in detail so that other organizations might consider replication in their areas.

The final performance report is due within 90 days of the completion of the project.

VII. Agency Contacts

For general questions about this announcement and for program technical assistance, applicants should contact their USDA Rural Development State Office at *http://www.rurdev.usda.gov/rbs/coops/rcdg/Contacts.htm*. The State Office can be reached by calling (202) 720–4323 and pressing ''1''. If an applicant is unable to contact their State Office, please contact a nearby State Office or the USDA Rural Development National Office at 1400 Independence Avenue, SW., Mail Stop 3250, Rm. 4016-South, Washington, DC 20250–3250, telephone: (202) 720–7558, e-mail: *cpgrants@wdc.usda.gov.*

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410, or call (866) 632–9992 (voice) or (202) 401–0216 (TDD). USDA is an equal opportunity provider and employer.

Dated: April 11, 2007.

Jackie J. Gleason,

Administrator, Rural Business-Cooperative Service.

[FR Doc. E7–7370 Filed 4–17–07; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

International Trade Administration

The President's Export Council: Meeting of the President's Export Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting via teleconference.

SUMMARY: The Manufacturing Council will hold a meeting via teleconference to deliberate a draft recommendation to the Secretary of Commerce regarding Alternative Energy.

DATES: May 4, 2007.

TIME: 12 p.m. (EDST).

FOR THE CONFERENCE CALL-IN NUMBER AND FURTHER INFORMATION, CONTACT: The Manufacturing Council Executive Secretariat, Room 4043, Washington, DC, 20230 (Phone: 202–482–1124), or visit the Council's Web site at *http://www.manufacturing.gov/council.*

Dated: April 13, 2007.

Sam Giller,

Staff Director and Executive Secretary, The Manufacturing Council.

[FR Doc. 07–1929 Filed 4–13–07; 4:45 pm]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration, North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Completion of Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of Completion of Panel Review of the final determination of dumping made by the Canada Border Services Agency, in the matter of Certain Copper Pipe Fittings Originating in or Exported From the United States of America, Secretariat File No. CDA–USA–2007–1904–01.

SUMMARY: Pursuant to the Notice of Motion to Terminate this panel review, which was filed with the Canadian Section of the NAFTA Secretariat on April 10, 2007, this panel review is completed.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: On March 2, 2007, Mueller Industries, Inc.

(Memphis, Tennessee), Streamline Copper & Brass Ltd. (Strathroy, Ontario) and affiliated companies within the Mueller Group filed a Request for Panel Review in the above referenced matter with the Canadian Section of the NAFTA Secretariat.

On April 10, 2007, Mueller Industries, Inc. (Memphis, Tennessee), Streamline Copper & Brass Ltd. (Strathroy, Ontario) and affiliated companies within the Mueller Group filed a Notice of Motion requesting termination of this panel review. No other interested person filed a request for Panel Review of this final determination. As of April 10, 2007, no Complaint or Notice of Appearance has been filed by any interested person. Therefore, pursuant to subrules 71(2) and 78(a) of the NAFTA Article 1904 Panel Rules, this Notice of Completion of Panel Review was effective on April 10, 2007.

Dated: April 12, 2007.

Caratina L. Alston,

United States Secretary NAFTA Secretariat.

[FR Doc. E7–7298 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 041107B]

Endangered Species; File No. 1595

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

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that Michael M. Hastings, University of Maine, 5717 Corbett Hall, Orono, Maine 04469, has been issued a permit to take shortnose sturgeon (*Acipenser brevirostrum*) for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978)281–9300; fax (978)281–9394.

FOR FURTHER INFORMATION CONTACT: Brandy Hutnak or Malcolm Mohead, (301)713–2289.

SUPPLEMENTARY INFORMATION: On January 16, 2007, notice was published in the **Federal Register** (72 FR 1706) that a request for a scientific research permit to take shortnose sturgeon had been submitted by the above-named individual. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

This permit authorizes Michael Hastings to annually capture, anesthetize, measure, weigh, sex (borescope), tissue sample, scan (for tags), Carlin tag, PIT tag, recover, and release up to 70 sub-adult and adult shortnose sturgeon annually. Additionally, up to 30 sub-adult and adult shortnose sturgeon, annually, would be fitted/implanted with an external/internal transmitter. This project also includes the annual lethal take of up to 50 shortnose sturgeon eggs. Up to 2 incidental mortalities of shortnose sturgeon each year is also being authorized. This research will help assess the distribution, abundance, and movements, as well as document spawning, of shortnose sturgeon in the Penobscot River System, Maine.

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: April 11, 2007.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–7378 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040607D]

Marine Mammals; File No. 555–1870

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

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that James T. Harvey, Ph.D., Moss Landing Marine Laboratories, 8272 Moss Landing Road, Moss Landing, CA has been issued a permit to conduct scientific research on harbor seals (*Phoca vitulina richardsi*).

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521;

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206)526–6150; fax (206)526–6426;

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907)586–7221; fax (907)586–7249; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Jaclyn Daly, (301)713–2289.

SUPPLEMENTARY INFORMATION: On December 29, 2006, notice was published in the **Federal Register** (71 FR 78407) that a request for a scientific research permit to take harbor seals had been submitted by the above-named individual. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The permit authorizes researchers to examine the biology and ecology and monitor health and condition of coastal populations of harbor seals in California, Oregon, Washington, and southeast Alaska over a 5-year period. Up to 670 harbor seals may be captured annually throughout the action area. An additional 2,910 individuals may be taken annually by harassment incidental to captures, scat collection, exposure to playback of vocalizations, and experimental disturbance activities. Up to 2 seal mortalities per year are authorized.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: April 10, 2007.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–7379 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 041207C]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council (Council) and NMFS will hold a Coastal Pelagic Species (CPS) Stock Assessment Review (STAR) Panel meeting to review assessment methods for Pacific mackerel.

DATES: The meeting is scheduled for Tuesday, May 1, 2007, from 10 a.m. to 5 p.m.; Wednesday, May 2, 2007, from 8 a.m. to 5 p.m.; and Thursday, May 3, 2007, from 8 a.m. to until business for the day is completed.

ADDRESSES: The STAR Panel will be held at the National Marine Fisheries Service, Southwest Fisheries Science Center, Green Room, 8604 La Jolla Shores Drive, La Jolla, CA 92037; telephone: (858) 546–7000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Burner, Pacific Fishery Management Council; telephone: (503) 820–2280; or Dr. Ray Conser, Southwest Fisheries Science Center; telephone: (858) 546–7000.

SUPPLEMENTARY INFORMATION: The purpose of the CPS STAR Panel meeting is to review draft stock assessment documents and any other pertinent information for Pacific mackerel, work with the Stock Assessment Team to make necessary revisions, and produce a STAR Panel report for use by the Council family and other interested persons for developing management recommendations for the 2007–08 Pacific mackerel fishery.

Although non-emergency issues not contained in this notice may arise during the STAR Panel, those issues may not be the subject of formal action during this meeting. Formal action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820–2280 at least 5 days prior to the meeting date.

Entry to the Southwest Fisheries Science Center (SWFSC) requires visitors to register with the front office each morning. A visitor's badge, which must be worn while at the SWFSC, will be issued to non-federal employees participating in the meeting. Since parking is at a premium at the SWFSC, car pooling, and mass transit are encouraged.

Dated: April 12, 2007.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E7–7299 Filed 4–17–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the President's Commission on Care for America's Returning Wounded Warriors

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a), Public Law 92–463, as amended, notice is hereby given of a forthcoming Meeting of the President's Commission on America's Returning Wounded Warriors. The purpose of the Committee meeting is to conduct briefings for the Commissioners. The meeting is open to the public, subject to the availability of space.

Interested persons may submit a written statement for consideration by the Committee and make an oral presentation of such. Persons desiring to make an oral presentation or submit a written statement to the Committee must notify the point of contact listed below no later than 18 April 2007. Oral presentations by members of the public will be permitted only on 23 April at 1 to 2 before the full Committee. Presentations will be limited to 5 minutes. Executive director and the Designated Federal official will select individuals for oral presentations and notify them in advance of the opportunity to make a 5 minute presentation to the Commission. Number of oral presentations to be made will depend on the number of requests received from members of the public. Each person desiring to make an oral presentation must provide the point of contact listed below with one (1) copy of the presentation by 18 April 2007, 5 p.m. and one copy of any material that is intended for distribution at the meeting. Persons submitting a written statement must submit one copy of the statement to the Commission staff by 5 p.m. POC Denise Dailey or Adrianne Holloway, toll free 877 588 2035 or Fax statements (703) 588–2046. Due to scheduling difficulties the Commission was unable to finalize its agenda in time to publish a **Federal Register** meeting notice of the 15-calendar days required by 41 CFR 102–3.150(a). Accordingly, the Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

DATES: Monday, April 23, 2007.

LOCATION: Main Conference Center, National Transportation Safety Board, 429 L'Enfant Plaza, SW., Washington, DC 20594.

FOR FURTHER INFORMATION ON SUBMITTING STATEMENTS CONTACT: Col Denise Dailey or Adrianne Hollway, toll free 877 588 2035 or Fax statements (703) 588–2046.

SUPPLEMENTARY INFORMATION: Meeting agenda.

23 April 2007

Not Open to the Public.

8:30 a.m., Welcome Commissioners, Administrative Remarks.

10 a.m., Public Session.

Presentations:

The Disability System.

12 p.m.–1 p.m., Lunch.

1–2, Public Forum Presentations.

2–2:45, System and Issues.

3–5, Presentations.

5–TBD, Wrap Up.

24 April

Walter Reed Visit.

Date and Times

Note: Exact order may vary.

Dated: April 12, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–1908 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Visitors Meeting

AGENCY: Department of Defense; Defense Acquisition University.

ACTION: Notice.

SUMMARY: The next meeting of the Defense Acquisition University (DAU) Board of Visitors (BoV) will be held at Defense Acquisition University, Fort Belvoir, VA. The purpose of this meeting is to report back to the BoV on continuing items of interest.

DATES: May 2, 2007 from 0900–1500.

ADDRESSES: Packard Conference Center, Defense Acquisition University, Bldg. 184, Fort Belvoir, VA 22060.

FOR FURTHER INFORMATION CONTACT: Ms. Christen Goulding at 703–805–5134.

SUPPLEMENTARY INFORMATION: The meeting is open to the public; however, because of space limitations, allocation of seating will be made on a first-come, first served basis. Persons desiring to attend the meeting should call Ms. Christen Goulding at 703–805–5134.

Dated: April 12, 2007.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 07–1907 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

[DOD–2007–OS–0035]

Privacy Act of 1974; Systems of Records

AGENCY: Defense Threat Reduction Agency.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Threat Reduction Agency proposes to alter a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on May 18, 2007 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Freedom of Information and Privacy Office, Defense Threat Reduction Agency, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6201.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda Carter at (703) 767–1771.

SUPPLEMENTARY INFORMATION: The Defense Threat Reduction Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2007, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 11, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

HDTRA 019

SYSTEM NAME:

Treaty Inspection Information Management System (November 9, 2006, 71 FR 65871).

CHANGES:

SYSTEM NAME:

Delete entry and replace with ''Arms Control Treaty Inspection Management System.''

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Add to entry ''passport numbers''.

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete from entry ''5 U.S.C. 4103, Establishment of training programs; Pub. L. 89–554 (September 6, 1966).''

Add to entry ''National Security Directive 41, Organizing to Manage On-site Inspection for Arms Control''.

PURPOSE(S):

Delete ''Treaty Monitoring and Inspection'' and replace with ''Arms Control.''

* * * * *

RETRIEVABILITY:

Add to entry ''passport numbers.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete ''TIIMS System Administrator'' replace with ''Arms Control Treaty Inspection Management System Administrator.''

NOTIFICATION PROCEDURE:

Delete ''TIIMS System Administrator'' replace with ''Arms Control Treaty Inspection Management System Administrator.''

RECORD ACCESS PROCEDURES:

Delete ''TIIMS System Administrator'' replace with ''Arms Control Treaty Inspection Management System Administrator.''

CONTESTING RECORD PROCEDURES:

Delete ''TIIMS System Administrator'' replace with ''Arms Control Treaty Inspection Management System Administrator.''

* * * * *

HDTRA 019

SYSTEM NAME:

Arms Control Treaty Inspection Management System.

SYSTEM LOCATION:

Defense Threat Reduction Agency, Room 4528, HQ Complex, 8725 John J. Kingman Road, VA 22060–6201.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals affiliated with the Defense Threat Reduction Agency, either by military assignment, civilian employment, or contractual support agreement. Individuals that are weapons inspectors, linguists, mission schedulers/planners, personnel assistants/specialists, portal rotation specialists, operation technicians, passport managers, clerical staff, and database management specialists.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number(SSN), date of birth, city/state/country of birth, education, gender, race, civilian or military member, military rank, security clearance, occupational category, job organization and location, emergency locator information, and passport numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 302, Delegation of Authority; National Security Directive 41, Organizing to Manage On-site Inspection for Arms Control; and E.O. 9397 (SSN).

PURPOSE(S):

To manage the Arms Control activities, including personnel resources, manpower/billet management, passport status, mission scheduling and planning, inspection team composition, inspector and transport list management, inspector

training, and inspection notification generation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of DTRA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES OF STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Records may be retrieved by name and/or Social Security Number (SSN), title, personnel type, and passport numbers.

SAFEGUARDS:

Records are maintained in areas accessible only to Defense Threat Reduction Agency personnel who must use the records to perform their duties. The computer files are password protected with access restricted to authorized users. Records are secured in locked or guarded buildings, locked offices, or locked cabinets during non-duty hours. Records are stored in a computer system with extensive intrusion safeguards.

RETENTION AND DISPOSAL:

Records are maintained for as long as the individual is assigned to Defense Threat Reduction Agency (DTRA). Upon departure from DTRA, records concerning that individual are removed from the active file and retained in an inactive file for two years and then deleted.

SYSTEM MANAGER(S) AND ADDRESS:

Arms Control Treaty Inspection Management System Administrator, Operations Enterprise, Operations Branch, Defense Threat Reduction Agency, Room 4528, HQ Complex, 8725 John J. Kingman Rd., Ft. Belvoir, VA 22060–6201.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to Arms Control Treaty Inspection Management System Administrator, Operations Enterprise, Operations Branch, Defense Threat Reduction Agency, Room 4528, HQ Complex, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6201.

Requests should contain individual's full name and Social Security Number (SSN).

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to Arms Control Treaty Inspection Management System Administrator, Operations Enterprise, Operations Branch, Defense Threat Reduction Agency, Room 4528, HQ Complex, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6201.

Requests should contain individual's full name and Social Security Number (SSN).

CONTESTING RECORD PROCEDURES:

The DTRA rules for accessing records and for contesting contents and appealing initial agency determinations are published in DTRA Instruction 5400.11; 32 CFR part 318; or may be obtained from the Arms Control Treaty Inspection Management System Administrator, Operations Enterprise, Operations Branch, Defense Threat Reduction Agency, Room 4528, HQ Complex, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6201.

RECORD SOURCE CATEGORIES:

Individual, DTR Officials, and assignment personnel.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–7357 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

[DOD–2007–OS–0036]

Privacy Act of 1974; System of Records

AGENCY: National Reconnaissance Office.

ACTION: Notice to add a system of records.

SUMMARY: The National Reconnaissance Office proposes to add a system of records to its inventory of system of records notice systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on May 18, 2007 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the FOIA/Privacy Official, National Reconnaissance Office, Information Access and Release, 14675 Lee Road, Chantilly, VA 20151–1715.

FOR FURTHER INFORMATION CONTACT: Contact the FOIA/Privacy Official at (703) 227–9128.

SUPPLEMENTARY INFORMATION: The National Reconnaissance Office systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2007, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I, 'Federal Agency Responsibilities for Maintaining Records About Individuals', to OMB Circular No. A–130, dated November 30, 2000.

Dated: April 11, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

QNRO–28

SYSTEM NAME:

Communications Security (COMSEC) Accounting Records.

SYSTEM LOCATION:

National Reconnaissance Office, Communications Directorate, 14675 Lee Road, Chantilly, VA 20151–1715.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Government civilians, military members, and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number (SSN), and COMSEC assets accountability records such as effective and supersession dates of crypto key, key quantities and format (i.e., electronic, hardcopy, etc.), COMSEC account number, software application versions loaded on the asset, location of materials/equipment, and location/site of assets information (corporation/site name, address, and contact information).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Security Act of 1947, as amended, 50 U.S.C. 401 *et seq.*; National

Security Telecommunication and Information Systems Security Instruction (NSTISSI) Number 4005; E.O. 10450, Security Requirements for Government Employees, as amended; and E.O. 9397 (SSN).

PURPOSE(S):

To support the NRO's Communications Security (COMSEC) mission. This system will be used as the accounting database to maintain and track NRO COMSEC assets and to identify those individuals authorized access to cryptographic materials/equipment, sites, and containers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the NRO as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routines Uses' published at the beginning of the NRO compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Individual's name, Social Security Number (SSN), and/or COMSEC account number.

SAFEGUARDS:

Records are stored in a secure, gated facility, guard, badge, and password access protected. Access to and use of these records is limited to staff whose official duties require such access.

RETENTION AND DISPOSAL:

Records relating to individuals access and authorization are destroyed 3 years after individual is debriefed. Keying material records are destroyed when 2 years old. COMSEC assets records are destroyed when removed from NRO accountability.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Communications Directorate, National Reconnaissance Office, 14675 Lee Road, Chantilly, VA 20151–1715.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the National Reconnaissance Office, Information Access and Release Center, 14675 Lee Road, Chantilly, VA 20151–1715.

Requests should contain individual's name and any aliases or nicknames, address, Social Security Number (SSN), current citizenship status, date and place of birth, and other information identifiable from the record.

In addition, the requester must provide a notarized statement or an unsworn declaration in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

If executed within the United States, its territories, possessions, or commonwealths: I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the National Reconnaissance Office, Information Access and Release Center, 14675 Lee Road, Chantilly, VA 20151–1715.

Requests should contain individual's name and any aliases or nicknames, address, Social Security Number (SSN), current citizenship status, date and place of birth, and other information identifiable from the record.

In addition, the requester must provide a notarized statement or an unsworn declaration in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

If executed within the United States, its territories, possessions, or commonwealths: I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).

CONTESTING RECORD PROCEDURES:

The NRO rules for accessing records, for contesting contents and appealing initial agency determinations are published in NRO Directive 110–3b and NRO Instruction 110–3–1; 32 CFR part 326; or may be obtained from the Privacy Act Coordinator, National Reconnaissance Office, 14675 Lee Road, Chantilly, VA 20151–1715.

RECORD SOURCE CATEGORIES:

Individual, COMSEC Officials, and other government agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–7358 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to delete a system of records.

SUMMARY: The Department of the Navy is deleting a system of records in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed actions will be effective without further notice on May 18, 2007 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: April 11, 2007.

C.R. Choate

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N05233–2

SYSTEM NAME:

Command Management Information System (CMIS) (March 18, 1997, 62 FR 12814).

REASON:

Command is being disestablished on 14 Apr 07. All files have been destroyed.

[FR Doc. E7–7359 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Realistic Bomber Training Initiative

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Record of decision.

SUMMARY: On March 20, 2007, the United States Air Force signed a Record of Decision for the Realistic Bomber Training Initiative Supplemental Environmental Impact Statement. This decision was based on information, analysis, and public comments contained in both the Environmental Impact Statement for the Realistic Bomber Training Initiative (**Federal Register** Notice of Availability February 4, 2000) and the Supplemental Environmental Impact Statement for the Realistic Bomber Training Initiative (**Federal Register** Notice of Availability published August 11, 2006), along with other relevant factors. After carefully considering the issues addressed in the Supplemental Environmental Impact Statement and the comments submitted, the Air Force decided not to change the decision described in the initial Record of Decision and to continue implementation of Alternative B of the Realistic Bomber Training Initiative. This alternative includes the use of appropriate training assets associated with Instrument Route IR–178/Lancer Military Operations Area. As indicated above, a Notice of Availability of the Final Supplemental Environmental Impact Statement was published in the **Federal Register** on August 11, 2006 (Volume 71, Number 155, Page 46220). The required 30-day waiting period for a Record of Decision has been completed.

FOR FURTHER INFORMATION CONTACT: Sheryl K. Parker, Headquarters Air Combat Command, A7ZP/ Comprehensive Planning Branch, 129 Andrews St., Suite 102, Langley AFB, VA 23655 or call (757) 764–9334.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. E7–7333 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability of the Draft Environmental Impact Statement (DEIS) for the Base Realignment and Closure (BRAC) 05 Realignment and Transformation Actions at Fort Benning, GA

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability (NOA).

SUMMARY: The U.S. Army announces the availability of the DEIS, which evaluates the potential environmental and socioeconomic impacts of transformation activities at Fort Benning, Georgia. These transformation proposed actions include implementation of the 05 BRAC Commission recommendations, the Global Defense Posture Realignment (GDPR) overseas re-stationing actions, Army Modular Force (AMF) initiatives, and other discretionary stationing activities.

DATES: The public comment period for the DEIS will end 45 days after publication of an NOA in the **Federal Register** by the U.S. Environmental Protection Agency.

FOR FURTHER INFORMATION CONTACT: Ms. Monica Manganaro, Fort Benning Public Affairs Office at (706) 545-3438, or Mr. Brandon Cockrell at (706) 545-3210 during normal business hours.

SUPPLEMENTARY INFORMATION: The Proposed Action and subject of the DEIS covers the construction activities and movement of personnel associated with the BRAC actions, proposed transformation activities at Fort Benning, Georgia, and follow-on operations and training.

The 2005 BRAC Commission recommended the relocation of the Armor Center and School from Fort Knox, Kentucky, to Fort Benning, as well as several other unit relocations, which would increase the Fort Benning population by approximately 4,486 military and 1,226 civilian personnel, and an annual student/trainee population of approximately 8,357. Fort Benning also proposes to implement other transformation actions as the Army undergoes restructuring to meet the demands of the 21st century. The AMF initiative involves the Army's transition from a division-centric design to a standard brigade organization. The reshaping of the domestic military force structure also includes provision for the return of units currently based overseas to United States installations as part of the GDPR. Finally, discretionary stationing actions (activations, inactivations, realignments and relocations) are proposed, which contribute to and are interrelated with the transformation process.

The proposed action will provide the facilities, infrastructure, and equipment needed to support the transformation activities at Fort Benning. All construction activities associated with the proposed action would occur on Fort Benning. The proposed construction, renovation, and expansion of administrative, supply/storage, maintenance, barracks, commercial services, community facilities, medical and dental, and recreation facilities, as well as associated infrastructure support, is focused on the already-established cantonment areas: Main Post, Kelley Hill, Sand Hill, and Harmony Church. Throughout the cantonment areas, new facility construction will be sited to coincide with and/or be a complement to existing missions, facility operations, and functions. In order to minimize potential impacts to the environment (e.g., avoiding sensitive species habitat), existing infrastructure would be used to the greatest extent possible, and transformation activities would be located on previously distributed/ developed areas. Training assets, in the form of ranges and maneuver areas, currently are found throughout the Installation. The proposed improvements/upgrades to existing ranges and maneuver areas and proposed new ranges were selected o align with these existing assets. Training range and maneuver area construction and operation/maintenance activities will occur on approximately 157,000 acres set aside for such activities.

In development of the DEIS, three alternatives were carried forward for analysis: (1) Transformation Alternative A, which entails cantonment area development, construction of small- and large-caliber weapons ranges, heavy maneuver areas and corridors, a driver's training course, off-road driver's training area, and vehicle recovery area to support the training range requirements; (2) Transformation Alternative B (the Army's Preferred Alternative), is similar to Transformation Alternative A with a combination of existing ranges and development of new tank training areas in the Good Hope area; and (3) the No Action Alternative, under which Fort Benning missions would continue as they were being performed in November 2005, when the BRAC Commission recommendations became law.

Environmental resources addressed in the DEIS include land use, aesthetics and visual resources, noise,

socioeconomics, transportation, utilities, hazardous and toxic substances and waste, air quality, water resources, geology and soils, biological and cultural resources, and safety.

The DEIS analyses indicate that implementation of Alternative A would have significant impacts on transportation; biological resources (vegetation, aquatic habitats, wildlife, and special status species); and cultural resources. Implementation of Alternative B (the preferred alternative) would have no significant impacts to visual and aesthetic resources; socioeconomics (economic development, housing, quality of life, environmental justice); noise; air quality; hazardous and toxic materials and waste (hazardous material storage, use and handling; contaminated sites); water resources (surface water, hydrogeology/groundwater, floodplains, and wetlands); geology and soils; biological resources (Unique Ecological Areas); safety; land use; or utilities. Alternative locations for some of the projects as presented in Alternative B would provide similar impacts and benefits as Alternative A in all resources except for biological (special status species), where the impacts to the Red-cockaded Woodpecker would be substantially less, and cultural (archaeological sites), where impacts would be greater. The No Action alternative provides the environmental baseline conditions for comparison to the impacts associated with the action alternatives.

The Army invites the public, local governments, and state and other Federal agencies to submit written comments or suggestions concerning the alternatives and analyses addressed in the DEIS. The public and government agencies also are invited to participate in a public meeting where oral and written comments and suggestions will be received. The public meeting will be held on May 10, 2007 from 6 p.m. to 9 p.m. at the Columbus, Georgia Convention and Trade Center, 801 Front Avenue, Room 205. Copies of the DEIS will be available for review at several local libraries prior to the public meeting. The DEIS may also be reviewed electronically at: *http://www.hqda.army.mil/acsim/brac/nepa_eis_docs.htm.*

Please send written comments on the DEIS to: Mr. John Brent, Fort Benning Directorate of Public Works, Environmental Management Division, Bldg #6 (Meloy Hall), Room 310, Fort Benning, GA 31905. E-mail comments should be sent to: *john.brent@benning.army.mil.*

Dated: April 10, 2007.

Addison D. Davis, IV,

Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health).

[FR Doc. 07–1916 Filed 4–17–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Defense Logistics Agency

[Requisition No. 07–007]

Removal of Low-Activity Contamination

AGENCY: Defense National Stockpile Center (DNSC), Defense Logistics Agency.

ACTION: Notice of availability of a finding of no significant impact for the removal of low-activity contamination.

SUMMARY: The Defense Logistics Agency announces the availability of the Finding of No Significant Impact (FONSI) for the removal of low-activity contamination resulting from storage of radioactive source material in the National Defense Stockpile of strategic and critical materials.

Stockpiles of commodities containing source material have been removed from DNSC depots at Curtis Bay, MD and Hammond, IN. At the Curtis Bay Depot, the commodities containing source material (columbium/tantalum, thorium nitrate, tungsten ore and concentrates, thorium hydroxide, thorium oxide, monazite sand, uranium pitchblende ore, and sodium sulfate) were previously stored in 16 of the original 59 warehouses. Since the middle 1980s, over 19,000 drums of thorium nitrate were stored in three warehouses. Previously the thorium nitrate stockpile was stored for short periods in six other warehouses on the site. At the Hammond Depot, the commodities containing source material (columbium/tantalum, thorium nitrate, monazite sands, sodium sulfate, and tungsten ore and concentrates) were previously stored in two of the three warehouses on the site. Cleanup of any residual contamination from storage of the commodities containing source material is one task DNSC must complete before its Nuclear Regulatory Commission license can be terminated.

Following evaluation of reasonable alternatives conducted by Oak Ridge National Laboratory on behalf of DNSC, DNSC will remove residual contamination and transfer the contaminants to a regulated disposal site. This disposal will be performed in a manner that will be safe, secure, and environmentally sound and minimizes radiation exposure and potential for risk to workers, the public, and the environment.

DATES: Notice of Availability of an Environmental Assessment and draft FONSI were published in the **Federal Register** on Friday, March 9, 2007 (Vol. 72, No. 46); comments received by April 9, 2007 were considered when preparing the final version of the FONSI.

The FONSI is available for review on the DNSC Web site (*https://www.dnsc.dla.mil/FINALFONSI.asp*).

FOR FURTHER INFORMATION CONTACT: Mr. Michael Pecullan, Phone (703) 767–7620 or e-mail: *michael.pecullan@dla.mil.*

Dated: April 10, 2007.

Cornel A. Holder,

Administrator, Defense National Stockpile Center.

[FR Doc. E7–7366 Filed 4–17–07; 8:45 am]

BILLING CODE 3620–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

[USN–2007–0027]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice of a new system of records.

SUMMARY: The Department of the Navy proposes to add a systems of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on May 18, 2007 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on April 6, 2007, to the House Committee on

Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: April 11, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N01533–1

SYSTEM NAME:

Navy Junior ROTC (NJROTC) Applicant/Instructor System.

SYSTEM LOCATION:

Naval Service Training Command, Citizenship Development, 250 Dallas Street, Suite A, Pensacola, FL 32508–5268.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Certified NJROTC instructor applicants and instructors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number (SSN), NJROTC Instructor Certification Application, Essay Questions, school name, Personal Appearance/Body Fat Measurements or most recent Physical Readiness Test (PRT), Photograph Submission Sheet, Interviewers Appraisal, Applicant Checklist, Certification Letter, NJROTC Instructor Evaluations, NJROTC Instructor Observation Report, Instructor Evaluation/Probation Letters, School Evaluation/Probation Letters, Resignation Letters, and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 2031, Junior Reserve Officers' Training Corps;

10 U.S.C. 5013, Secretary of the Navy; and E.O. 9397 (SSN).

PURPOSE(S):

To provide a record of the qualifications, experience, effectiveness, and related information for those serving, and those seeking certification, as NJROTC instructors.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folder and electronic storage media.

RETRIEVABILITY:

Name, Social Security Number (SSN), and/or name of school.

SAFEGUARDS:

Records are stored in locked cabinets. Access to building controlled through utilization of swipe card. All guests escorted. Access to electronic documentation is limited to authorized personnel who have a requisite access card and is password protected.

RETENTION AND DISPOSAL:

Initial applications for Instructors are maintained until considered by certification board. Those not certified are destroyed after 90 days.

Instructor records, including records of their certification are destroyed 6 years after instructor ceases teaching NJROTC.

Individual Certification records not teaching NJROTC are destroyed 6 years from applicant's active duty retirement date.

Decertified/Revoked instructor records are destroyed 1 year after decertification/revocation date.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding Officer, Naval Service Training Command, Citizenship Development, 250 Dallas Street, Suite A, Pensacola, FL 32508–5268.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Commanding Officer, Naval Service Training Command, Citizenship Development (NJROTC), 250 Dallas Street, Suite A, Pensacola, FL 32508–5268.

Requests should contain individual's full name, Social Security Number (SSN), duty position, if currently an NJROTC instructor, and name of school. If no longer an NJROTC instructor, they should provide dates of service as an instructor.

The request must be signed, include current address, and telephone number.

RECORDS ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Commanding Officer, Naval Service Training Command, Citizenship Development (NJROTC), 250 Dallas Street, Suite A, Pensacola, FL 32508–5268.

Requests should contain individual's full name, Social Security Number (SSN), duty position, if currently an NJROTC instructor, and name of school. If no longer an NJROTC instructor, they should provide dates of service as an instructor.

The request must be signed, include current address, and telephone number.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records and contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual, NJROTC administrative personnel, and school district personnel.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–7360 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[USN–2007–0026]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Navy is altering a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on May 18, 2007 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2007, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 11, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N01740–1

SYSTEM NAME:

Family Dependent Care Program (September 22, 2006 71 FR 55443).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''All Navy personnel serving on active duty or in the Ready Reserve who are single parents and who have primary or shared physical custody and who is married to and resides with an individual who is neither the natural or adoptive parent of the service member's minor child or children (i.e. step parent); service member whose minor children do not reside with the natural or adoptive parent or other person who has legal interest in the custody of the minor children; both members of a dual military couple where one or both have primary or shared physical custody of minor children; service members who are legally responsible for an adult family member who is incapable of providing for themselves in the absence of the service member; and family circumstances or other personal status changes in which the service member becomes legally and primarily responsible for the care of another person.

This system also covers members of the U.S. Marine Corps and Coast Guard when assigned to a Navy unit.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Add ''Social Security Number (SSN).''

* * * * *

PURPOSE(S):

Delete entry and replace with ''To identify and ensure that single military members and military couples with dependents have made adequate dependent care arrangements; to ensure the member is worldwide assignable; to ensure combat readiness and document a plan for the care of family members in the event of a medium or long term absence; to evaluate compliance with DoD and Navy programs requiring Family Care Plans; and to ensure family members are cared for during deployments, reserve mobilizations, temporary duty, etc. and that arrangements are in place for the financial well being of family members covered by the Family Care Plan during separations.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete ''(N151)'' and replace with ''(N135)''.

* * * * *

N01740–1

SYSTEM NAME:

Family Dependent Care Program.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List (SNDL) that is available at *http://doni.daps.dla.mil/sndl.aspx.*

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Navy personnel serving on active duty or in the Ready Reserve who are single parents and who have primary or shared physical custody and who is married to and resides with an individual who is neither the natural or adoptive parent of the service member's minor child or children (i.e. step parent); service member whose minor children do not reside with the natural or adoptive parent or other person who has legal interest in the custody of the minor children; both members of a dual military couple where one or both have primary or shared physical custody of minor children; service members who are legally responsible for an adult family member who is incapable of providing for themselves in the absence of the service member; and family circumstances or other personal status changes in which the service member becomes legally and primarily responsible for the care of another person.

This system also covers members of the U.S. Marine Corps and Coast Guard when assigned to a Navy unit.

CATEGORIES OF RECORDS IN THE SYSTEM:

Family Care Plan package which includes NAVPERS 1740/6—Family Care Plan Certificate, NAVPERS 1740/7—Family Care Plan Arrangements, Family Care Plan Checklist, Social Security Number (SSN), address, copies of powers of attorney, legal documents, allotment information, financial information, counseling forms, etc.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; OPNAVINST 1740.4C, U.S. Navy Family Care Policy and E.O. 9397 (SSN).

PURPOSE(S):

To identify and ensure that single military members and military couples with dependents have made adequate dependent care arrangements; to ensure the member is worldwide assignable; to ensure combat readiness and document a plan for the care of family members in the event of a medium or long term absence; to evaluate compliance with DoD and Navy programs requiring Family Care Plans; and to ensure family members are cared for during deployments, reserve mobilizations, temporary duty, etc. and that arrangements are in place for the financial well being of family members covered by the Family Care Plan during separations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

Name and Social Security Number (SSN).

SAFEGUARDS:

Files are maintained in file cabinets under the control of authorized

personnel during working hours; the office space in which the file cabinets are located is locked outside official working hours. Automated records are password protected.

RETENTION AND DISPOSAL:

Records are maintained by the commanding officer or his designated representative for the period the individual is assigned to that organization. Records are updated annually or when family circumstances or other personal status changes. File follows member with each new assignment. Once affiliation with the Navy is complete, records are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: Director, Personal Readiness and Community Support (N135), Office of the Chief of Naval Personnel, 5720 Integrity Drive, Millington, TN 38055–6000.

RECORD HOLDER:

Commanding officer or designated representative of the naval activity where assigned. Official mailing addresses are published in the Standard Navy Distribution List (SNDL) that is available at *http://doni.daps.dla.mil/sndl.aspx.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Commanding Officer of the activity where assigned. Official mailing addresses are published in the Standard Navy Distribution List (SNDL) that is available at *http://doni.daps.dla.mil/sndl.aspx.*

Requests should contain individual's full name, Social Security Number (SSN), dates assigned at that activity, and must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Commanding Officer of the activity where assigned. Official mailing addresses are published in the Standard Navy Distribution List (SNDL) that is available at *http://doni.daps.dla.mil/sndl.aspx.*

Requests should contain individual's full name, Social Security Number (SSN), dates assigned at that activity, and must be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and contesting contents, and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–7361 Filed 4–17–07; 8:45 am]

BILLING CODE 5001–06–P

DENALI COMMISSION

Denali Commission Fiscal Year 2007 Work Plan Request for Comments

AGENCY: Denali Commission.

ACTION: Denali Commission Fiscal Year 2007 Work Plan request for comments.

SUMMARY: The Denali Commission (Commission) is an independent Federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and in training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission was created in 1998 with passage of the October 21, 1998 Denali Commission Act (Act) (Title III of Pub. L. 105–277, 42 U.S.C. 3121). The Denali Commission Act requires that the Commission develop proposed work plans for future spending and that the annual Work Plan be published in the **Federal Register** for a 30 day period, providing an opportunity for public review and comment.

This **Federal Register** notice serves to announce the 30 day opportunity for public comment on the Denali Commission Work Plan for Federal Fiscal Year 2007.

DATES: Comments and related material must be received by May 18, 2007.

ADDRESSES: Submit comments to the Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Mr. Krag Johnsen, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–1414. E-mail: *kjohnsen@denali.gov.*

Background

The Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to develop a well-trained labor force employed in a diversified and sustainable economy, and to build and ensure the operation and maintenance of Alaska's basic infrastructure.

By creating the Commission, Congress mandated that all parties involved partner together to find new and innovative solutions to the unique infrastructure and economic development challenges in America's most remote communities.

Pursuant to the Denali Commission Act, as amended, the Commission determines its own basic operating principles and funding criteria on an annual federal fiscal year (October 1 to September 30) basis. The Commission outlines these priorities and funding recommendations in an annual Work Plan.

Pursuant to the Act, the Work Plan is first provided in draft for Commissioner discussion, recommended via motion by the Commission for publication in the **Federal Register** for a period of no less than 30 days and for broad dissemination for written public comment. Commission staff is responsible for compiling written public comment and forwarding it to the Commission's Federal Co-Chair (Mr. George J. Cannelos).

The Federal Co-Chair then adopts a final version of the Work Plan, which includes, to the degree the Federal Co-Chair deems appropriate, modifications, additions and deletions based on the policy and program recommendations of the full Commission and public comment. The final version of the Work Plan is adopted by the Commission, forwarded to the Secretary of Commerce and through the Secretary of Commerce to the Federal Office of Management and Budget (OMB), on behalf of the Federal Co-Chair. The Work Plan is also disseminated widely to Commission program partners including, but not limited to the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), and the United States Department of Agriculture—Rural Development (USDA–RD).

The Work Plan authorizes the Federal Co-Chair to enter into grant agreements, award grants and contracts and obligate the federal funds identified by appropriation below.

In past Federal fiscal year the Commission would provide a draft Work Plan for Commissioners' review, discussion, and forwarding to the **Federal Register** and public posting in the early fall or late winter. A revised final version of the plan would then be released by the Federal Co-Chair in late spring or early summer. However, due to the Continuing Resolution (CR) that affected all federal appropriations in FY 07, and which was not passed until February 15, 2007, the publication of

the draft Work Plan has not followed the typical timeline.

The Federal Co-Chair may enter into grants for the FY 07 period after publication of the draft Work Plan, and before all public comment is received. This is necessary to ensure that construction, barge and project schedules are not compromised and that project costs do not escalate due to delays. If appropriations are passed within ordinary fiscal year timelines outlined above, this step would ordinarily not be necessary.

The Commission is also in the process of completing its first ever Program Evaluation, and will be using its findings to embark on a Strategic Planning initiative. References in this document to ''the Strategic Planning'' process refer to that activity which the Commission will begin undertaking in the summer of calendar year 2007.

FY 07 Appropriations Summary

The Denali Commission receives several federal funding sources (identified by the varying colors in the table below). These fund sources, commonly referred to as ''appropriations,'' are governed by the following general principles:

- In FY 07 there are no project specific earmarks in any appropriations;
- Energy and Water Appropriations (commonly referred to as Commission ''Base'' funding) is eligible for use in all programs, but has historically been used substantively to fund the Energy Program.
- The Energy Policy Act of 2005 established new authorities for the Commission's Energy Program, with an emphasis on renewable and alternative energy projects. No new funding accompanied the Energy Policy Act, and Congressional direction has indicated that the Commission should fund renewable and alternative Energy Program activities from the available FY 07 ''Base'' appropriation.
- All other appropriations outlined below may be used only for the specific program area and may not be used across programs. For instance, Health Resources and Services Administration (HRSA) funding, which is appropriated for the Health Facilities Program, may not be moved to the Economic Development Program.

A 1% federal rescission was passed in the CR for FY 07. The application of this rescission is noted below. It is applied at the appropriation level, as is the Commission's 5% overhead. In instances where the rescission and/or overhead differs from the rates discussed above (1% and 5% respectively) it is due to the requirements related to that appropriation. For example, TAPL is not from an appropriation, so it is not subject to a rescission.

Final transportation appropriations received will be slightly reduced due to agency modifications, reductions and fees determined by the U.S. Department of Transportation.

Some appropriation figures are estimates, pending receipt of funds, and clarification of the passage of the February 15, 2007 CR. Program appropriations that fall into this category have been identified by the term ''estimate.''

The table below provides the following information, by appropriation:

- Total FY 07 Appropriations:

These are the figures that appear in the rows entitled ''FY 07 Appropriation'' and are the original appropriation amounts which not include federal rescissions or Commission overhead deductions. These appropriations are identified by their source name (i.e., ''Energy and Water Appropriation; USDA, Rural Utilities Service, etc.)

- Total FY 07 Program Available Funding:

These are the figures that appear in the rows entitled ''FY 07 Appropriations—Program Available'' and are the amounts of funding available for program(s) activities after all federal rescissions and Commission overhead has been deducted.

- Commission Staff Recommended Program Funding:

These are the figures that appear in the rows entitled with the specific Program and Sub-Program area, and are the amounts of funding, within each appropriation, recommended by Commission staff for program funding (i.e., from the ''Base'' appropriation staff has recommended funding the Economic Development Program in the amount of $3,000,000).

- Subtotal of Program Funding:

These are the figures that appear in the rows entitled ''subtotal'' and are the subtotals of all Commission staff recommendations within a given appropriation (i.e., the sub-total of recommendations in the ''Base'' is $47,025,000). The subtotal must always equal the Total FY 07 Program Available Funding.

The last column on the table also provides the appropriation information for FY 06, and serves as a program comparison for recommendations in FY 07.

DENALI COMMISSION FY 07 APPROPRIATIONS FUNDING TABLE

FY 07 Energy & Water Appropriation	$50,000,000
FY 07 Energy & Water Appropriations (''Base'')—Program Available (less 1% federal rescission and 5% Commission overhead)	47,025,000
Energy Program: Bulk fuel, RPSU, etc.	26,025,000
Energy Program: Alternative & renewable energy	5,000,000
Teacher Housing Program: Design & construction	5,000,000
Health Facilities: Planning, design & construction	8,000,000
Economic Development Program: Various	3,000,000
Multi-Use Program	0
Public Broadcasting Program	0
Washeteria Program	0
Sub-total	47,025,000
FY 07 USDA, Rural Utilities Service (RUS)	15,000,000
FY 07 USDA—Rural Utilities Service (RUS)—Program Available (less 4% overhead) ESTIMATE	14,400,000
Energy Program: High energy cost communities	14,400,000
Sub-total	14,400,000
FY 07 Trans Alaska Pipeline Liability (TAPL) Trust	4,227,257
FY 07 Trans Alaska Pipeline Liability (TAPL)—Program Available (less 5% overhead) ESTIMATE	4,015,895

DENALI COMMISSION FY 07 APPROPRIATIONS FUNDING TABLE—Continued

Energy Program: Bulk fuel	4,015,895
Sub-total	4,015,895
FY 07 DHHS—Health Resources & Services Administration (HRSA)	39,680,000
FY 07 DHHS-Health Resources & Services Administration (HRSA)—Program Available (less 1% federal rescission and 5% Commission overhead)	37,319,040
Health Program: Primary Care clinic design, planning, construction	29,119,040
Health Program: Behavioral Health	5,063,000
Health Program: Primary Care in Hospitals	2,500,000
Health Program: Equipment	637,000
Health Program: Hospital Designs	0
Health Program: Elder Supportive Housing/Assisted Living	0
Sub-total	37,319,040
FY 07 Department of Labor (DOL)	6,944,000
FY 07 Department of Labor (DOL)—Program Available (less 5% Commission overhead)	6,530,832
Training Program: Construction, Operations & Maintenance Training	4,000,000
Training Program: Management Training For Commission Projects	1,000,000
Training Program: Youth Initiatives	1,000,000
Training Program: Construction, Operations & Maintenance Training of ''Other Public Infrastructure''	530,832
Sub-total	6,530,832
FY 07 Federal Transportation Administration (FTA)	12,500,000
FY 07 Federal Highway Administration (FHWA)	12,500,000
FY 07 Transportation (less 5% Commission overhead)—ESTIMATE	24,000,000
Transportation Program: Docks & Harbors	11,500,000
Transportation Program: Roads	12,500,000
Sub-total	24,000,000
FY 07 USDA, Solid Waste	750,000
FY 07 USDA—Solid Waste—Program Available (less 5% Commission overhead)	705,375
Solid Waste Program: planning, design and construction	705,375
Sub-total	705,375
Total FY 07 Appropriations—ESTIMATE	141,601,257

FY 07 Program Summaries

The following section provides narrative discussion, by each of the Commission Programs identified for FY 07 funding in the table above, in the following categories:

- Program Background
- Program Approach
- FY 07 Program Funding
- FY 07 Program Implementation
- FY 07 Outputs & Outcomes

The following programs, or sub-program areas, which have been funded by the Commission in previous federal fiscal years are not recommended for funding in FY 07 and do not appear in the narrative below:

- Washeterias
- Health Facilities:
  - Elder Supportive Housing/Assisted Living
  - Domestic Violence
  - Hospital Designs
- Multi-Use Facilities
- Public Broadcasting

In addition to the FY 07 funded program activities; the last section of the narrative provides an update on the Commission's Government Coordination Program. The Program is not funded by Commission appropriations, but is an integral component of the Commission's mission, the success of other programs, and the legacy of the Commission's work in Alaska.

Energy Program

Program Background: The Energy Program is the Commission's oldest program and is often identified, along with the Health Program, as a ''legacy'' program. The Program focuses on bulk fuel (BFU) and rural power system upgrades/power generation (RPSU) across Alaska.

Since 1999, approximately 48% of all Commission funds have been allocated to the energy program ($337 million). This amount includes all energy projects in the legacy program, as well as some alternative energy projects. In FY 06, $21.7 million went to legacy BFU, $17.6 million to RPSU plus $4.9 million to wind and $2.3 million to interties related to the RPSU projects. The needs in the bulk fuel and power generation projects are presently estimated at $198 million and $211 million, respectively, in 2004 construction costs. At FY 06 funding rates, it will take another eight to nine years for BFU and ten to eleven years for RPSU before these programs are completed. The Commission has also funded a very successful program of competitively selected energy cost reduction-alternative energy projects. In three completed rounds of funding, approximately $6 million in grant funds have leveraged $8.1 million in participant funding, with estimated life-cycle cost savings (generally diesel fuel avoided over the life of the project) of $29 million.

The Energy Policy Act of 2005 established new authorities for the Commission's Energy Program, with an emphasis on alternative and renewable energy projects, energy transmission, including interties, and fuel transportation systems. Although the 2005 Energy Policy Act did not include specific appropriations, the Commission is expected to carry out the intent of the

Act through a portion of its ''Base'' funding. To date, the Commission has co-funded a number of renewable projects, including hydroelectric facilities, a geothermal power plant, a biomass boiler, and a number of diesel-wind power generation systems. The FY 07 draft Work Plan offers a strategy to rebalance the Energy Program in both legacy and renewable systems. About 94% of electricity in rural communities which receive Power Cost Equalization (PCE) payments is produced by diesel and about half the fuel storage in most villages is used for the power plants. Any alternative means of generating power can reduce the capacity needed for fuel storage. This reduces capital costs and operations and maintenance (O&M) and repair and renovation (R&R) costs for fuel storage facilities) and may reduce the cost of power to the community.

Thus, a renewable project sometimes is proposed in conjunction with a deficiency list project to reduce the dependence on diesel fuel, and the concomitant fuel storage requirements. So too, an intertie, can remove the need for a new power plant, and reduce fuel storage requirements in the intertied communities. Therefore, the legacy Program may include these types of energy infrastructure too. Each community and project must be evaluated holistically. Program partners also perform initial due diligence and Investment Policy screenings, as well as assisting in development of the business plans for the participants as the designs are underway. The Program is dynamic: Priorities fluctuate throughout the year, based on design decisions, due diligence and investment policy considerations, site availability the timing of funding decisions, etc.

Program Approach: The Energy Program has historically used a ''universe of need'' model to determine project and program funding. Specifically, the Program is focused on using the existing statewide deficiency lists of bulk fuel facilities and power generation/distribution systems to prioritize project funding decisions. A program partnership model is utilized for project management and partners are actively involved in the design and construction of projects. Partners coordinate project funding requests with the Commission to balance the relative priority or urgency of bulk fuel and power generation needs against available funding, readiness of individual communities and project participants for the project(s), and capacity of the partners to carry out the work.

FY 07 Program Funding: The Commission has historically directed that the Program continue to concentrate on completion of the legacy program of BFU and RPSU for communities on the statewide deficiency lists. In FY 07 the Program has received funding requests exceeding $93 million, primarily for deficiency list projects.

As has always been the case in the Program, the funding requests exceed funds available. The legacy of BFU and RPSU remain integral to completing the Program mission, but they cannot and should not be accomplished in a vacuum which prevents applying appropriate technology and reducing rural dependence on diesel for energy needs. A well-balanced portfolio of BFU, RPSU and renewable/alternative energy projects will accomplish the overall program mission, and result in increased savings over the long term.

Provide up to $26,025,000 to BFU and RPSU from the ''Base'' appropriation; and up to $5,000,000 from the ''Base'' appropriation to alternative/renewable energy projects for competitive selection and requiring a 1:1 match to Commission funding.

Provide approximately $14,400,000 to BFU and RPSU in communities with extremely high energy costs >275% of the national average from the USDA–RUS appropriation; and $4,015,895 to the BFU sub-program area from the TAPL funding. A total of up to $49,440,895 in FY 07 program funding is planned.

In FY 07 the Commission intends to establish a new Energy Advisory Committee to make recommendations on future partners, organizations, and projects. The Committee will be comprised of a broad selection of individuals that are knowledgeable about energy in Alaska.

FY 07 Outputs & Outcomes: Program funding at the level identified above is likely to result in the following outputs:

- Completion of 2 interties
- 1 wind-diesel project
- 10 RPSU and 10 BFU projects
- Continuing design efforts
- Small number of energy cost reduction projects
- Small number of renewable/alternative energy projects

Completion of code-compliant bulk fuel storage facilities and power plant or distribution systems by definition has improved access to energy and created more safe and healthy rural communities. Program partners have collected anecdotal information on improved efficiencies and reduced costs at their upgraded facilities for the last several years. Additionally, the Commission has begun to gather and collate data more formally to quantify savings realized by individual projects and the Program.

Additional outcome measurements will be developed for the Program, and will largely be determined during the upcoming Strategic Planning process. Specifically, it is intended that the Program will develop more outcomes related to access and cost reduction.

Health Facilities Program

Program Background: The Denali Commission Act was amended in 1999 to provide for the, ''planning, constructing and equipping of health facilities.'' Since 1999, the Health Facilities Program has been methodically investing in the planning, design and construction of primary care clinics across Alaska.

Primary care clinics have remained the ''legacy'' priority for the Program. However, in 2003 the ''Other Than'' primary care component of the Program was adopted in response to Congressional direction to fund a mix of other health and social service related facility needs. Over time, the Program has developed Program sub-areas such as Behavioral Health Facilities, Domestic Violence Facilities, Elder Housing, Primary Care in Hospitals, Emergency Medical Services Equipment and Hospital Designs.

Program Approach: The Program utilizes a ''universe of need'' model for primary care and a competitive selection process for other sub-program areas. In 1999 the Program created a deficiency list for primary care clinics, which totaled 288 communities statewide in need of clinic replacement, expansion and/or renovation. Currently, 70 clinics have been completed (either new construction or renovation), 33 are in construction and 62 are in planning/design.

The Program is guided by the Health Steering Committee, an advisory body comprised of the following membership organizations: The State of Alaska, Alaska Primary Care Association, the Alaska Native Tribal Health Consortium, the Alaska Mental Health Trust Authority, the Alaska Native Health Board, the Indian Health Service, the Alaska State Hospital and Nursing Home Association, and the University of Alaska.

Projects are recommended for funding if they demonstrate project readiness, which includes the completion of all due diligence requirements. This includes an approved business plan, community plan, site plan checklist, completed 100% design, documentation

of cost share match, and realistic ability to move the project forward in a given construction season.

FY 07 Program Funding: The language in the HRSA Appropriations bill for FY06 read as follows: The Committee provides $39,680,000 for the Denali Commission. The fiscal year 2005 comparable level was $39,680,000 and the administration did not request funding for this program in fiscal year 2006. These funds support construction and renovation of health clinics, hospitals and social service facilities in rural Alaska, as authorized by Public Law 106–113, to help remote communities in Alaska develop critically needed health and social service infrastructure for which no other funding sources are available, thereby providing health and social services to Alaskans in remote rural communities as they are in other communities throughout the country. The Committee expects the Denali Commission to allocate funds to a mix of rural hospital, clinic, long-term care and social service facilities, rather than exclusively on clinic funding.

Provide a total of up to $44,699,103 in clinic construction is provided. Of this total an estimated $24,211,201 are ready to move forward to construction and another $20,487,902 have met most due diligence requirements and have a strong likelihood of being construction ready this summer. In addition, some 40 communities are actively completing planning and design requirements and will likely be ready for the 2008 construction season. The Program's model of planning, design and construction has been very successful, and has resulted in the significant need described above.

No funds are provided for hospital designs. The Commission has been actively engaged in hospital designs in partnership with the Indian Health Service for several years. While the Commission recognizes the ongoing need for construction funding for hospitals, the recommendation is that the Commission's health funding be limited only to design need.

Provide a total of up to $5,063,000 for the sub-program area of behavioral health. The behavioral health facilities sub-program has successfully developed a functional process for allowing organizations to expand capacity for serving a specific population of youth in residential treatment with the goal of keeping them closer to their homes in Alaska.

Provide a total of up to $2,500,000 to the primary care in hospitals sub-program area. Primary care improvements in hospitals focus on the primary care repair, renovation and equipment needs within a hospital setting. Project selection, prioritization and due diligence determined through a competitive process.

Provide a total of up to $637,000 to the emergency medical services (EMS) equipment sub-program. Since its inception the Health Program has funded EMS equipment needs across the state of Alaska. This sub-program area receives wide support and cost share matching from other funding organizations in Alaska. A condition for funding is that projects proceed to award within a timely manner, consistent with other program areas.

The FY 07 Program funding strategy is based on a total of $37,119,040 in HRSA appropriations and additionally up to $8,000,000 in ''Base'' appropriations for a total of up to $47,680,000 in program funding.

FY 07 Outputs & Outcomes: Program funding at the level identified above is likely to result in the following outputs:

- Clinics
  - 18 construction projects
- Behavioral Health
  - 4 construction projects
- Primary Care in Hospitals
  - 9 equipment/renovation projects
- EMS Equipment
  - Unknown; pending selection

Outcome goals related to increased access and reduction in cost are anticipated for FY 2008 and will be developed in response to the Program Evaluation and pending Strategic Planning efforts.

Training Program

Program Background: In a majority of rural communities unemployment rates exceed 50% and personal capita income rates are over 50% below the national average. When job opportunities in rural Alaska do become available, rural residents often lack the skills necessary to compete and often lose those jobs to people from outside the community, region or even state. With the limited number of jobs available the Commission believes it is imperative to ensure that local residents have the skills and knowledge necessary to work on the construction of projects funded by the Denali Commission. In addition the Commission builds sustainability into the development of infrastructure by providing training for the long term management, operations and maintenance of facilities and thus increasing local employment at the same time.

The Program's mission is to increase the employment and wages of unemployed or underemployed Alaskans through training for careers in construction, operations and maintenance of public facilities.

The Program is also guided by the following principles:

- Priority on training for construction, operations and maintenance of public infrastructure
- Training will be tied to a job
- Training will encourage careers not short term employment
- Funding will support a ''Training System''

Program Approach: To date the Commission has dedicated training funds to the careers associated with infrastructure development and long-term sustainability in rural Alaska. The Commission has funded construction, operations and maintenance training in communities statewide with large success.

The Training Program's primary purpose is to support the Commission's investment in infrastructure development by providing training for the careers related to the Commission infrastructure programs (such as Energy and Health Facilities).

Following are the Program's priorities related to training activities that support infrastructure:

- *Priority #1—Training for Construction, Operations and Maintenance of Commission Projects*

Description: At the core of the Training Program is the continuation of training related to the construction, operations and maintenance of Commission funded projects. The Commission training program centers on the goal of creating employment opportunities for local residents to construct Commission funded projects and develop the skills necessary to operate and maintain Commission facilities.

- *Priority #2—Management Training for Commission Projects*

Description: A sustainable Commission facility not only requires the skills training for operations and maintenance of the physical facility but also requires the management training related to the operations of such a facility. The skills of planning, reporting and accounting are all essential to the survival of rural infrastructure.

- *Priority #3—Youth Initiatives in Support of Commission Projects*

Description: Preparing Alaskans youth for careers that support the Denali Commission's mission of building sustainable communities.

• *Priority #4—Construction, Operations and Maintenance Training of ''Other Public Infrastructure''*

Description: In order to build capacity in communities, regionally and statewide the Commission invests in the training for projects that are not funded by the Commission directly. This investment increases the skills and knowledge of rural residents in order to ultimately maintain Commission projects and all other publicly funded projects.

Historically the Commission has provided funding directly to organizations that are able to deliver results in the priority areas as described above. These organizations have typically been selected by the Commission directly or through competitive requests for proposals managed by partner organizations

FY 07 Program Funding: The Commission expects to have available $6,530,832 in FY 07 funding for the Training Program. This funding is provided by the U.S. Department of Labor to support the program. The Commission anticipates receipt of this funding in July 2007.

Provide up to the following funding amounts in the following general categories pursuant to its priority areas:

Priority—1 Construction, Operations and Maintenance Training of Denali Commission Projects	$4,000,000
Priority—2 Management Training for Commission Projects	1,000,000
Priority—3 Youth Initiatives	1,000,000
Priority—4 Construction, Operations and Maintenance Training of Other Public Infrastructure''	530,832

In FY 07 the Commission intends to establish a new Training Advisory Committee to make recommendations on the partners, organizations, and projects that should receive FY 07 funding under the priority areas outlined above. This Advisory Committee will be comprised of a broad representation of individuals that are knowledgeable of and have experience in training in rural Alaska.

FY 07 Outcomes & Outputs: Program funding at the level identified above is likely to result in the following outputs:

- Over 1300 people trained
- Cost per participant trained is less than $5,000
- 5% increase in employment 7–12 months after Commission funded training
- 35% increase in annual earnings 7–12 months after Commission funded training

The following longer term outcome goals have been identified for the Program:

- 35% increase in annual earnings 5 years after Commission funded training

Additional outcome goals will be developed in response to the Program Evaluation and pending Strategic Planning efforts.

Transportation

Program Background: On August 10, 2005, the President signed into law new highway program reauthorization legislation titled Safe, Accountable Flexible Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU). This Act provides the Commission with $15 million annually for fiscal years 2005–2009 for a Denali Access System program. The Act also provides the Commission $10 million annually for Fiscal Years 2005–2009 for docks, harbors and related waterfront development projects. The Act also outlined the array of road projects Denali Access System is designed to target, including rural community streets and roads; roads between rural communities; roads between rural communities and state highway system; and roads to access resource development.

The Act requires the formation of an Advisory Committee to advise the Commission with members appointed by the Governor of Alaska. On November 11, 2005, Governor Murkowski announced appointments to the Denali Access Systems Transportation Advisory Committee (TAC). The nine member committee includes by law, four members who represent existing regional native corporations, native non-profit entities, and tribal governments and four members who represent rural Alaska regions or villages. The committee chair is Denali Commission Federal Co-Chair, George J. Cannelos.

As a result of a TAC-directed public outreach and agency coordination effort, the $24,000,000 program has now begun to focus attention on two important transportation needs: roads and boardwalks, and barge landing moorage systems. Village connector roads and roads to local and regional resources will continue to receive significant attention, but to the extent practical each year, local roads and boardwalks in small rural communities will receive primary attention. In the waterfront development program, docks and harbors in small coastal communities will continue to receive attention, but there is a significant need for barge landings in coastal and riverine communities to improve operational safety and efficiencies. This class of project will receive primary consideration each year to the extent funding and construction schedules allow.

Another evolution in Program development, especially in the road Program, has been a shift from maximizing financial leveraging opportunities with other transportation agencies, to fully funding, as necessary, the program's highest priority projects. In FY 06, the $23 million transportation program leveraged almost $100 million in projects. In coming years, while striving to leverage funding opportunities, an emphasis on priorities over funding partnerships will likely reduce the overall program joint-fund total.

Program Approach: The TAC is a central feature of the amendments to the Denali Commission Act of 1998 amendments that define the Denali Access System. Section 309 defines key committee responsibilities that include: Recommend transportation priorities and funding strategies; develop public involvement and coordinating planning programs; develop annual capital budget recommendations; and coordinate multi-region projects.

The TAC reviews project nominations on a semi-annual basis, once in December for project selections and once during the summer to monitor project development.

In addition to meeting transportation-specific criteria and processes, the Program fully incorporates Denali Commission policies including a commitment to sustainable community projects, and a commitment to the Commission's Investment Policy.

FY 07 Program Funding: The Commission will provide up to $12,500,000 to the roads component of the Program. Local roads projects have immediate benefits for health and quality of life, while having minimal impact on the environment. This program element includes boardwalks in many river delta and coastal areas of the state.

Provide up to $11,500,000 to the waterfront development component of the program. In the waterfront development program, small community harbor rehabilitation and

expansion needs are recognized and will continue to receive attention. However, as demonstrated in several analyses since 2000, including the Alaska Department of Transportation and Public Facilities Yukon-Kuskokwim Plan and the Northwest Alaska Plan, and the U.S. Army Corps of Engineers Yukon-Kuskokwim Regional Port Study, barge landing design and construction is the most urgent unmet maritime need in rural Alaska.

FY 07 Outcomes & Outputs: Program funding at the level identified above is likely to result in the following outputs:

- Roads
  - 9 projects in design; 15 projects in construction
- Water Front Development
  - 9 projects in design; 11 projects in construction

Outcome goals related to increased access and reduction in transportation costs are anticipated for FY 08 and will be developed in response to the Program Evaluation and pending Strategic Planning efforts.

Solid Waste

Program Background: The Commission began receiving solid waste funding in FY 06. The Commission partners with USDA Rural Development to address deficiencies in solid waste disposal sites which threaten to contaminate rural drinking water supplies.

Proper solid waste collection, processing and disposal are an essential public service that often presents a difficult challenge in rural Alaska. Due to several factors, including limited rural Alaska local government budgets, community remoteness, limited transportation infrastructure and obstacles posed by Alaska's severe climate, solid waste service is a prominent widespread deficiency in the context of Alaska's wide array of environmental issues and public health and quality of life issues.

Program Approach: The program relies on a competitive RFP process to select and identify projects, and utilizes a multidiscipline review panel to ensure that projects meet all Commission due diligence and policy requirements. Typically this RFP process occurs once or twice in a given year depending on need and project eligibility.

Beginning in FY 07 funds will be granted to program partners and will not be awarded directly to individual recipients.

FY 07 Program Funding: Provide up to $705,375 to conduct a competitive RFP process to select eligible projects and program partners.

FY 07 Outputs & Outcomes: Program funding at the level identified above is likely to result in the following outputs:

- Funding of up to 15 projects

Outcome goals related to increased access and reduction in cost are anticipated for FY 08 and will be developed in response to the Program Evaluation and pending Strategic Planning efforts.

Teacher Housing

Program Background: Teaching in rural Alaska can be one of the most rewarding and challenging professions. A critical issue for rural teachers is finding safe, affordable housing during the school year. Housing availability varies by community from newer adequate homes, to old housing units with multiple safety and structural problems, to a lack of enough available housing, requiring teachers to double-up or even live in the school.

Teacher turnover rates are high in rural Alaska, with many teachers citing unavailable or inadequate housing as a factor in their decision to move. The quality of education received by students is impacted by teacher retention. By improving the availability and quality of housing for teachers, the Commission strives to also increase the quality of education received by the next generation of Alaskans.

In FY 04, Congress directed the Commission to address the teacher housing needs in rural Alaska. The Commission launched a statewide survey of 51 school districts and rural education attendance areas to identify and prioritize the teacher housing needs throughout the state.

Program Approach: The Commission utilizes a program partnership model to implement the teacher housing program. An annual RFP process identifies eligible projects and other funding sources, such as debt service, available to fill the gap between the project's capacity to carry debt and the total development cost of the project. Acquisition, rehabilitation, new construction, and multi-site rehabilitation are eligible development activities under this program.

FY 07 Program Funding: Provide up to $5,000,000 from the ''Base'' appropriation for ongoing funding of the Teacher Housing Program, via competitive annual RFP.

FY 07 Outputs & Outcomes: Program funding at the level identified above is likely to result in the following outputs:

- Funding of up to 20 units (renewal & replacement and new construction)

Outcome goals related to increased access and reduction in cost are anticipated for FY 08 and will be developed in response to the Program Evaluation and pending Strategic Planning efforts.

Economic Development

Program Background: Since its earliest days as a territory of the United States, Alaska has contributed to the economy of America, largely through supply of raw materials or partially processed products. Now Alaska's abundant natural resources, from fossil fuel and mineral products to timber and fish, must compete in the global marketplace. Innovation and entrepreneurship have become critical to business success.

One of the purposes of the Commission is economic development. The Commission firmly believes that sustainable economic development for Alaska's rural communities, like that of the rest of America, will be generated in the private, commercial sector, not within government. To that end, the Commission supports the development of public infrastructure upon which the private sector creates jobs and wealth, and helps ensure that good businesses and business ideas have a chance to become long-term, self-sustaining enterprises.

Over the history of the Program, the Commission has supported and advanced a wide-array of economic development program activities ranging from community profile mapping to supporting innovative models for lending, and equity investment in Alaska.

Program Approach: The Program has a documented history of involvement with numerous partners and program activities. However, the Program has lacked a cohesive and well-articulated focus, a project selection process, adequate funding, staffing levels, and has yet to implement statutory guidance.

FY 07 Program Funding: Provide up to $3,000,000 from the ''Base'' appropriation for the Program.

In FY 07 the Commission intends to establish a new Economic Development Advisory Committee to make recommendation on the partners, organizations, and projects that should receive FY 07 funding. In addition this Committee, in concert with the Commission would provide priority areas for funding and project focus, similar to the process of priority identification in the Training Program. The Committee will be comprised of a broad selection of individuals that are knowledgeable about economic development in rural Alaska, including

Alaska Natives, and a majority of whom shall be from rural Alaska.

FY 07 Outputs & Outcomes: Specific outputs have not been recorded for the Program. To date output data has been generated on a project-by-project basis as it related to economic investment, development, job creation, income enhancement, quality of life, etc.

Output and outcome goals related to increased access and reduction in cost are anticipated for FY 08 and will be developed in response to the Program Evaluation and pending Strategic Planning efforts, and in concert with the development of the Program's Advisory Committee.

Government Coordination

Program Background: The Commission is charged with the special role of increasing the effectiveness of government programs by acting as a catalyst to coordinate the many federal and state programs that serve Alaska. The Commission led the way by committing state, federal, and non-profit organizations and agencies to this effort in jointly signing a Memorandum of Understanding (MOU). This MOU outlines the role of agencies in coordinating resources and efforts in areas such as community planning, sustainability, information technology and data sharing and coordination of pre-construction activities. This MOU served as the basis for the creation of several multi-agency work groups and cooperative projects that have served to increase the agencies' collective effectiveness. The MOU was amended in 2003 with increased participation from both the state and federal partners.

FY 07 Program Goals: The Commission is planning to begin work on a revised MOU in FY 07 and anticipates further broadening the partner and signatory list to include members of the philanthropic, development and Community Development Quota (CDQ) groups. In addition the Commission is working actively with other federal and state partners to evaluate the current MOU workgroups, update membership as necessary and continue critical discussions related to infrastructure, community planning and collaborative funding and project selection.

Dated: April 10, 2007.

George J. Cannelos,

Federal Co-Chair.

[FR Doc. E7–7344 Filed 4–17–07; 8:45 am]

BILLING CODE 3300–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Amended Notice

AGENCY: United States Election Assistance Commission.

ACTION: Notice of public meeting.

DATE AND TIME: Wednesday, April 18, 2007, 1 p.m.–4 p.m.

PLACE: Westin Crown Center, Room: Washington Park 3, One East Pershing Road, Kansas City, Missouri 64108, (816) 474–4400.

AGENDA: The Commission will receive a presentation on and consider adopting a Spanish translation glossary of election terminology. The Commission will elect a vice-chair and will receive a presentation on the development of its election management guidelines. The Commission will also consider other administrative matters.

This meeting will be open to the public.

PERSON TO CONTACT FOR INFORMATION: Bryan Whitener, Telephone: (202) 566–3100.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. 07–1943 Filed 4–16–07; 1:46 pm]

BILLING CODE 6820–KF–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–128–000]

Cheyenne Plains Gas Pipeline Company, L.L.C.; Notice of Application

April 12, 2007.

Take notice that on April 2, 2007, Cheyenne Plains Gas Pipeline Company, L.L.C. (Cheyenne Plains), P.O. Box 1087, Colorado Springs, Colorado 80944, filed an application at Docket No. CP07–128–000, pursuant to Section 7(c) of the Natural Gas Act (NGA), for a certificate of public convenience and necessity authorizing the construction and operation of a new compression facility, the Kirk Compressor Station, comprised of one 10,310 horsepower compressor unit, to be located in Yuma County, Colorado. The project is designed to transport up to 70,000 Dth per day on the Cheyenne Plains' mainline, all as more fully set forth in the application.

The application is on file with Commission and open for public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* and follow the instructions or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any questions regarding this Application should be directed to Richard Derryberry, Director, Regulatory Affairs, Cheyenne Plains Gas Pipeline Company, L.L.C., P.O. Box 1087, Colorado Springs, Colorado, 80944 at (719) 520–3788 or by fax at (719) 667–7534. Or Craig V. Richardson, Vice President and General Counsel, Cheyenne Plains Gas Pipeline Company, L.L.C.; P.O. Box 1087, Colorado Springs, Colorado, 80944 at (719) 520–4829 or by fax at (719) 520–4898.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the

Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

The Commission strongly encourages electronically filings of comments, protests and interventions via the Internet in lieu of paper. See, 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site *www.ferc.gov* under the ''e-Filing'' link.

Comment Date: May 3, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7308 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–95–000]

Enstor Gulf Coast Storage, LLC; Notice of Application

April 12, 2007.

On March 2, 2007, as supplemented on March 7, 2007, Enstor Gulf Coast Storage, LLC (Enstor) 20333 State Highway 249, Suite 400, Houston, Texas 77070, filed (1) an application in Docket No. CP07–94–000, pursuant to section 7(c) of the NGA and the Commission's regulations, for a certificate of public convenience and necessity authorizing the operation of a Gulf Coast storage pool that will aggregate storage capacity obtained from discrete affiliated and non-affiliated service providers, and in combination with off-system interstate transportation capacity acquired on five interstate pipelines, will provide storage and storage related services to the interstate market; and (2) an application in Docket No. CP07–96–000 for a blanket transportation certificate under Part 284 Subpart G of the Commission's regulations, to provide open access storage and storage related services at market based rates with pregranted abandonment.

Take notice that in that same filing, Enstor also requested in Docket No. CP07–95–000 a blanket certificate under Part 157 Subpart F of the Commission's regulations. This authorization would allow Enstor to engage in any of the activities described in sections 157.208 through 157.218 without having to obtain case-specific authorizations to undertake routine construction activities, to make miscellaneous rearrangements of its facilities, to change receipt and delivery points, and to render certain storage services.

These filings are available for review at the Commission's Washington, DC offices or may be viewed on the Commission's Web site at *http://www.ferc.gov/* using the ''e-Library'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *ferconlinesupport@ferc.gov* or Telephone: 202–502–6652; Toll-free: 1–866–208–3676; or for TTY, contact (202) 502–8659.

Any questions regarding these applications should be directed to Joseph H. Fagan of Heller Ehrman LLP, 1717 Rhode Island Avenue, NW., Washington, DC 20036–3001, or phone (202) 912–2162, or FAX (202) 912–2020, or e-mail *joseph.fagan@hellerehrman.com*.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this Project. First, any person wishing to obtain legal status by becoming a party to the proceeding for this project should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10) by the comment date, below. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project and/or associated pipeline. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 285.2001(a)(1)(iii) and the instructions on the Commission's Web site under the

''e-filing'' link. The Commission strongly encourages electronic filings.

Comment Date: April 19, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7309 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2539–033]

Erie Boulevard Hydropower, L.P.; Notice Rejecting Rehearing Request

April 12, 2007.

On February 15, 2007, the Commission issued an order on offer of settlement and issuing new license. *Erie Boulevard Hydropower, L.P.,* 118 FERC ¶ 61,101. On March 19, 2007, Adirondack Hydro Development Corporation and Green Island Power Authority, jointly, filed a request for rehearing in this proceeding.

Under section 313(a) of the Federal Power Act, 16 U.S.C. 825*l*(a)(2000), a request for rehearing may be filed only by a party to the proceeding. Green Island is not a party to this proceeding.[1] Therefore, the request for rehearing is rejected as to Green Island Power Authority.

This notice constitutes final agency action. Requests for rehearing by the Commission of this rejection notice must be filed within 30 days of the date of issuance of this notice, pursuant to 18 CFR 385.713 (2006).

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7313 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

April 11, 2007.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC07–75–000.

Applicants: Walton County Power, L.L.C.; Washington County Power, LLC; Effingham County Power, LLC; MPC Generating, LLC; Progress Genco Ventures, LLC; Progress Ventures, Inc.; Mackinaw Power, L.L.C.

Description: Progress Ventures, Inc. et al. submit an application for authorization under section 203 of the FPA and request for waivers.

Filed Date: 04/04/2007.

Accession Number: 20070409–0198.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 25, 2007.

Docket Numbers: EC07–76–000.

Applicants: J–Power USA Investment Co., Ltd.; John Hancock Life Insurance Company.

Description: J–Power USA Investment Co., Ltd. and John Hancock Life Insurance Co. submit a joint application for authorization to transfer ownership interest in exempt wholesale generators etc.

Filed Date: 04/06/2007.

Accession Number: 20070411–0074.

Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Take notice that the Commission received the following electric rate filings.

Docket Numbers: ER04–1232–007.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits its Substitute Sixth Revised Sheet 161A to FERC Electric Tariff, Fourth Revised Volume 1.

Filed Date: 04/05/2007.

Accession Number: 20070410–0170.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER06–880–006; ER07–632–001.

Applicants: PJM Interconnection, L.L.C.

Description: Neptune Regional Transmission System, LLC and PJM Transmission Owners Administrative Committee submit revisions to Schedule 14 to their Open Access Transmission Tariff filed on 3/16/07.

Filed Date: 04/04/2007.

Accession Number: 20070411–0143.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 25, 2007.

Docket Numbers: ER06–613–003.

Applicants: ISO New England Inc.; New England Power Pool.

Description: ISO New England, Inc. submits a report on the status of the implementation of certain reserve market changes that were included as part of Phase II of the Ancillary Services Market project.

Filed Date: 04/02/2007.

Accession Number: 20070411–0142.

Comment Date: 5 p.m. Eastern Time on Monday, April 23, 2007.

Docket Numbers: ER07–597–001.

Applicants: Montana Generation, LLC.

Description: Montana Generation, LLC submits an amendment to its tariff, Substitute Sheet 1 et al. to FERC Electric Tariff, Original Volume 1 to incorporate the requested changes pursuant to the Commission's 2/16/06 order.

Filed Date: 04/05/2007.

Accession Number: 20070410–0169.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER07–710–000.

Applicants: Peoples Energy Services Corporation.

Description: Integrys Energy Group Inc. on behalf of Peoples Energy Services Corp submits a revised market-based rate tariff etc.

Filed Date: 03/23/2007.

Accession Number: 20070409–0191.

Comment Date: 5 p.m. Eastern Time on Friday, April 13, 2007.

Docket Numbers: ER07–717–000.

Applicants: Entergy Services, Inc.

Description: Entergy Services, Inc on behalf of the Entergy Operating Companies submits a notice of adoption of North American Electric Reliability Council's revised Transmission Loading Relief Procedures compliance filing.

Filed Date: 04/05/2007.

Accession Number: 20070410–0172.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER07–718–000.

Applicants: Pepperell Realty LLC.

Description: Pepperell Realty LLC submits a notice of cancellation of FERC Electric Tariff, Original Volume 1.

Filed Date: 04/05/2007.

Accession Number: 20070410–0171.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER07–719–000.

Applicants: Xcel Energy Operating Companies.

Description: Xcel Energy Operating Companies submits Third Revised Sheet 27 et al. to FERC Gas Tariff, First Revised Volume 1 to its Joint Open Access Transmission Tariff, First Revised Volume 1 pur to Part 35 of FERC's Regulations.

Filed Date: 04/05/2007.

Accession Number: 20070410–0173.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER07–722–000.

Applicants: South Carolina Electric & Gas Company.

Description: South Carolina Electric & Gas Co submits Original Tariff Sheet 374 et al. adopting the North American Electric Reliability Council Transmission Loading Relief Procedures to comply with FERC's Order 676.

Filed Date: 04/05/2007.

Accession Number: 20070411–0047.

Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

[1] On June 28, 2006, the Secretary denied Green Island's late motion to intervene in the School Street relicensing proceeding.

Docket Numbers: ER07–723–000.
Applicants: Old Dominion Electric Cooperative, Inc.
Description: Old Dominion Electric Cooperative submits rate schedule for providing cost-based Reactive Power and Voltage Control from Generation Sources Service etc.
Filed Date: 04/06/2007.
Accession Number: 20070411–0145.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–724–000.
Applicants: Old Dominion Electric Cooperative, Inc.
Description: Old Dominion Electric Cooperative submits amended rate schedule for providing cost-based Reactive Power and Voltage Control from Generation Sources Service.
Filed Date: 04/06/2007.
Accession Number: 20070411–0061.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–725–000.
Applicants: Old Dominion Electric Cooperative, Inc.
Description: Old Dominion Electric Cooperative submits an amended rate schedule for providing cost-based Reactive Power and Voltage Control from Generation Sources Service.
Filed Date: 04/06/2007.
Accession Number: 20070411–0062.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–726–000.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator, Inc submits revisions to its Open Access Transmission Tariff to incorporate the latest approved version re Transmission Loading Relief procedure.
Filed Date: 04/05/2007.
Accession Number: 20070411–0144.
Comment Date: 5 p.m. Eastern Time on Thursday, April 26, 2007.

Docket Numbers: ER07–727–000.
Applicants: Entergy Services, Inc.
Description: Entergy Operating Companies submits an amendment to the Entergy System Agreement.
Filed Date: 04/06/2007.
Accession Number: 20070411–0066.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–729–000.
Applicants: Old Dominion Electric Cooperative, Inc.
Description: Old Dominion Electric Cooperative submits a rate schedule for providing cost-based Reactive Power and Voltage Control from Generation Sources Service etc.
Filed Date: 04/06/2007.
Accession Number: 20070411–0064.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–730–000.
Applicants: Public Service Electric and Gas Company; PSEG Energy Resources & Trade LLC.
Description: Public Service Electric & Gas Company et al. submit request for waivers of affiliate standards and authorizations for sales etc.
Filed Date: 04/06/2007.
Accession Number: 20070411–0063.
Comment Date: 5 p.m. Eastern Time on Friday, April 27, 2007.

Docket Numbers: ER07–731–000.
Applicants: Florida Power & Light Company.
Description: Florida Power & Light Co submits a new Rate Schedule 305, Agreement for Generator Balancing Service with DeSoto County Generating Co, LLC.
Filed Date: 04/09/2007.
Accession Number: 20070411–0067.
Comment Date: 5 p.m. Eastern Time on Monday, April 30, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified *Comment Date*. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will e-File a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,
Secretary.
[FR Doc. E7–7315 Filed 4–17–07; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Declaration of Intention and Soliciting Comments, Protests, and/or Motions to Intervene

April 11, 2007.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Declaration of Intention.
b. *Docket No:* DI07–7–000.
c. *Date Filed:* March 22, 2007.
d. *Applicant:* Rodney Medlicott.
e. *Name of Project:* U.S. Survey 295 Micro Hydro Project.
f. *Location:* The proposed U.S. Survey 295 Micro Hydro Project will be located on an unnamed creek and on Wolf Creek, tributary to Moser Bay, near the town of Ketchikan, Alaska, affecting T. 73 S., R. 91 E, sec. 7, Copper River Meridian.
g. *Filed Pursuant to:* Section 23(b)(1) of the Federal Power Act, 16 U.S.C. § 817(b).
h. *Applicant Contact:* Rodney Medlicott, Post Office Box 383, Hope, ID 83836; telephone: (208) 264–5337; e-mail: *dakota@imbris.net.*
i. *FERC Contact:* Any questions on this notice should be addressed to Henry Ecton, (202) 502–8768, or E-mail address: *henry.ecton@ferc.gov.*
j. *Deadline for filing comments, protests, and/or motions:* May 11, 2007.

All documents (original and eight copies) should be filed with: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and/or interventions may be filed electronically

via the Internet in lieu of paper. Any questions, please contact the Secretary's Office. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov.*

Please include the docket number (DI07–7–000) on any comments, protests, and/or motions filed.

k. *Description of Project:* The proposed run-of-river U.S. Survey 295 Micro Hydro Project would include: (1) A 7-foot-long, 3-foot-high diversion structure, with a 10-inch pipe directing water into a 2,000 gallon plastic tank; (2) an 8-inch-diameter, 1,000-foot-long pipe, connected to the powerhouse; (3) a 12-foot-square powerhouse containing a 10-kW turbine/generator; (4) an 800-foot-long transmission line, connected to an existing residence; and (5) appurtenant facilities. The project will not be connected to an interstate grid, and will not occupy any tribal or federal lands.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Locations of the Application:* Copies of this filing are on file with the Commission and are available for public inspection. This filing may be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link, select ''Docket#'' and follow the instructions. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTESTS'', and/or ''MOTIONS TO INTERVENE'', as applicable, and the Docket Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7310 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–540–000]

High Island Offshore System, L.L.C.; Notice of Informal Settlement Conference

April 12, 2007.

Take notice that an informal settlement conference will be convened in this proceeding commencing at 10 a.m. (EST) on Thursday, April 19, 2007 at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Arnold Meltz (202–502–8649).

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7314 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at Southwest Power Pool Board of Directors/Members Committee Meetings and Southwest Power Pool Regional State Committee Meeting

April 11, 2007.

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool (SPP) Board of Directors/Members Committee and SPP Regional State Committee noted below. Their attendance is part of the Commission's ongoing outreach efforts.

SPP Regional State Committee: April 23, 2007 (1 p.m.–5 p.m.), The Skirvin Hilton Hotel, One Park Avenue, Oklahoma City, Oklahoma 73102, 405–272–3040.

Board of Directors/Members Committee: April 24, 2007 (8:30 a.m.–3 p.m.), The Skirvin Hilton Hotel, One Park Avenue, Oklahoma City, Oklahoma 73102, 405–272–3040.

The discussions may address matters at issue in the following proceedings:

Docket No. ER04–1232, Southwest Power Pool, Inc.
Docket No. ER05–799, Southwest Power Pool, Inc.
Docket No. ER05–526, Southwest Power Pool, Inc.
Docket No. ER05–1416, Southwest Power Pool, Inc.
Docket No. EL06–83, Southwest Power Pool, Inc.
Docket No. ER06–432, Southwest Power Pool, Inc.
Docket No. ER06–448, Southwest Power Pool, Inc.
Docket No. ER06–451, Southwest Power Pool, Inc.
Docket No. ER06–1047, Southwest Power Pool, Inc.
Docket No. ER06–767, Southwest Power Pool, Inc.
Docket Nos. ER06–1485 and ER07–266, Xcel Energy Services, Inc.
Docket No. ER06–1488, Oklahoma Gas & Electric Company.
Docket No. ER06–1463, Empire District Electric Company.
Docket No. ER07–385, American Electric Power Service Corporation.

Docket No. ER06–1471, Westar Energy, Inc.
Docket No. ER06–1467, Southwest Power Pool, Inc.
Docket No. EL06–71, *Associated Electric Cooperative, Inc.* v *Southwest Power Pool.*
Docket No. ER07–14, Southwest Power Pool, Inc.
Docket Nos. ER07–211 and ER07–709, Southwest Power Pool, Inc.
Docket No. ER07–314, Southwest Power Pool, Inc.
Docket No. ER07–319, Southwest Power Pool, Inc.
Docket No. ER07–603, Southwest Power Pool, Inc.

These meetings are open to the public.

For more information, contact John Rogers, Office of Energy Markets and Reliability, Federal Energy Regulatory Commission at (202) 502–8564 or *john.rogers@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7311 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Guidelines for Submission of CDs, DVDs, and Other Electronic Media

April 12, 2007.

Take notice that the Commission is issuing notice of guidelines for submission of CDs, DVDs and other electronic media. An increasing number of traditionally paper documents submitted to the Federal Energy Regulatory Commission (FERC) are now accompanied by one or more CDs, DVDs or other electronic media that contain all or part of the submission, or contain supplements to the submission. These guidelines address such submissions and require that, among other things, the CDs/DVDs contain the entire submission.

These guidelines apply to documents that cannot be submitted through any of the Commission's existing electronic gateways: The eFiling system, the eForms system, or the Electric Quarterly Reports (EQR) system. They thus are primarily intended for larger filings and those filings that contain Privileged, Critical Energy Infrastructure (CEII), or Non-Internet Public (NIP) information.

Persons following these guidelines will be granted an automatic waiver of the number of paper copies and may instead submit the requisite number of copies of a filing on CD/DVD and reduce the number of paper copies to an original and two copies in most cases. These guidelines do *not* change any FERC requirements concerning service of submissions on customers, parties, or other persons.

The guidelines will be posted at: *http://www.ferc.gov/help/submission-guide.asp* and updated when necessary to reflect revised procedures or changes in media.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–7312 Filed 4–17–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8301–1]

Clean Air Act Operating Permit Program; Petition for Objection to South Dakota State Operating Permit for Pope & Talbot, Inc., Lumber Mill, Spearfish, SD

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of direct final order.

SUMMARY: This notice announces that the EPA Administrator has responded to a citizens' petition asking EPA to object to a State operating permit issued by the South Dakota Department of Environmental and Natural Resources (DENR). Specifically, the Administrator has partially granted and partially denied the petition submitted by Jeremy Nichols, and the other Petitioners, to object to the issuance of the operating permit issued to Pope and Talbot, Inc., for its lumber mill, located in Spearfish, South Dakota.

Pursuant to section 505(b)(2) of the Clean Air Act (Act), Petitioners may seek judicial review of those portions of the petition which EPA denied in the United States Court of Appeals for the appropriate Circuit. Any petition for review shall be filed within 60 days of the date this notice appears in the **Federal Register**, pursuant to section 307(d) of the Act.

ADDRESSES: You may review copies of the final Order, the petition, and other supporting information at the Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129 after April 16, 2007. EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the copies of these documents. You may view these documents Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays. If you wish to examine these documents, you should make an appointment at least 24 hours before the visiting day. The final Order is also available electronically at the each of the following addresses: *http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitions/pope_talbot_decision2006.pdf.* and *http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitiondb2006.htm.*

FOR FURTHER INFORMATION CONTACT: Christopher Ajayi, Environmental Engineer, Air and Radiation Program, Office of Partnerships and Regulatory Assistance, Mail Code 8P–AR, U.S. Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129, telephone (303) 312–6320, or e-mail at *ajayi.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION: The Clean Air Act (Act) affords EPA a 45-day period to review and object to, as appropriate, operating permits proposed by State permitting authorities. Section 505(b)(2) of the Act authorizes any person to petition the EPA Administrator within 60 days after the expiration of this review period to object to State operating permits if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the State, unless the Petitioner demonstrates that it was impracticable to object during the comment period or that the grounds for the objection or other issue arose after this period.

On April 11, 2006, the EPA received a petition from Petitioners requesting that EPA object to the issuance of the Title V operating permit issued by South Dakota Department of Environmental and Natural Resources (DENR) to Pope and Talbot, Inc., to operate a lumber mill in Spearfish, South Dakota (''the Facility'').

The Petitioners request that EPA object to the issuance of the proposed permit and raise the following objections as the bases for their petition:

1. Permit fails to ensure compliance with Carbon Dioxide (CO) emission limits,

2. Permit lacks sufficient periodic monitoring of CO emissions,

3. Permit may need ''schedule of compliance'' because it fails to ensure that CO emission limits are below Prevention of Significant Deterioration (PSD) levels and thus not in compliance with PSD requirements,

4. Permit fails to ensure compliance with South Dakota State

Implementation Plan (SIP) and Title V permit modification procedure in accordance with state of South Dakota's rule,

5. Permit fails to require sufficient periodic opacity monitoring,

6. Permit fails to require prompt reporting of opacity deviations,

7. Permit does not require ''prompt'' reporting,

8. Permit fails to subject the facility to Maximum Achievable Control Technology (MACT), and

9. Permit contains other Conditions (5.4, 6.1, 6.3 and 6.5) that warrant objection by the Administrator.

On March 22, 2007, the Administrator issued an Order partially granting and partially denying the petition. The Order explains the reasons for partially granting the petition and directs DENR to revise and/or remove specific permit language and/or discussions in the Statement of Basis. The Order also directs DENR to provide additional information to support certain permit Conditions. Finally, the Order explains the reasons for denying the petitioners' remaining claims.

Dated: April 4, 2007.

Kerrigan G. Clough,

Deputy Regional Administrator, Region 8.

[FR Doc. E7–7351 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OH–166–1; FRL–8301–6]

Adequacy Status of the Youngstown, OH, Submitted 8-Hour Ozone Redesignation and Maintenance Plan for Transportation Conformity Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of adequacy.

SUMMARY: In this notice, EPA is notifying the public that we have found that the motor vehicle emissions budgets (MVEBs) for volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the Youngstown, Ohio area (Columbiana, Mahoning, and Trumbull Counties) are adequate for use in transportation conformity determinations. Ohio submitted these budgets with an 8-hour ozone redesignation request and maintenance plan on December 4, 2006, and February 20, 2007. As a result of our finding, Youngstown, Ohio must use the MVEBs from the submitted 8-hour ozone redesignation and maintenance plan for future conformity determinations.

DATES: This finding is effective May 3, 2007.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Life Scientist, Criteria Pollutant Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *Maietta.anthony@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we'', ''us'' or ''our'' is used, we mean EPA.

Background

Today's notice is simply an announcement of a finding that we have already made. On March 21, 2007, EPA Region 5 sent a letter to the Ohio Environmental Protection Agency stating that the 2009 and 2018 MVEBs for the Youngstown area, which were submitted with the 8-hour ozone redesignation request and maintenance plan, are adequate. Receipt of these MVEBs was announced on EPA's conformity Web site, and no comments were submitted. The finding is available at EPA's conformity Web site: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm*.

The adequate 2009 and 2018 MVEBs, in tons per day (tpd), for VOC and NO_X for Youngstown are as follows:

	2005 MVEB (tpd)	2018 MVEB (tpd)
VOC	19.58	10.36
NO_X	33.71	13.29

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to a State Implementation Plan (SIP) means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). We have described our process for determining the adequacy of submitted SIP budgets in our July 1, 2004, preamble starting at 69 FR 40038, and we used the information in these resources while making our adequacy determination. Please note that an adequacy review is separate from EPA's completeness review, and it also should not be used to prejudge EPA's ultimate approval of the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

The finding and the response to comments are available at EPA's conformity Web site: *http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm*.

Authority: 42 U.S.C. 7401–7671q.

Dated: April 5, 2007.

Walter W. Kovalick,

Acting Regional Administrator, Region 5.

[FR Doc. E7–7367 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–0103; FRL–8124–4]

Pyridate; Notice of Receipt of Requests to Voluntarily Cancel and to Terminate Uses of Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of a request by a registrant to voluntarily cancel its registrations for all products containing the pesticide pyridate. This notice announces receipt by EPA of a request from the registrant Syngenta Crop Protection, Inc., to cancel all remaining pyridate product registrations. The request would terminate the last pyridate products registered for use in the United States. The last remaining pyridate products registered under FIFRA Section 3 were cancelled in 2004 for failure to pay the required annual maintenance fee (See Unit II for **Federal Register** cite), but there are several FIFRA 24(c) Special Local Needs registrations (for weed control on mint) that are still active. Syngenta Crop Protection, Inc., the registrant for all of the currently registered FIFRA 24(c) products, has requested cancellation of all of the remaining pyridate 24(c) products. EPA intends to grant this request at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the request, or unless the registrant withdraws their request within this period. Upon acceptance of this request, any sale,

distribution, or use of products listed in this notice will be permitted only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before October 15, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2007–0103, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2007–0103. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-8195; fax number: 703-308-7070; e-mail address: *pates.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background on the Receipt of Requests to Cancel Registrations to Delete Uses

This notice announces receipt by EPA of a request from the registrant Syngenta Crop Protection, Inc., to cancel all remaining pyridate product registrations. Pyridate is a terrestrial herbicide classified as a pyrazole thiocarbonate chlorine.

In a letter dated January 12, 2007, Syngenta Crop Protection, Inc. requested that EPA cancel all product registrations and terminate all uses of

the pesticide product registrations identified in this notice (Table 1). The request would terminate the last pyridate products registered for use in the United States. The last remaining pyridate products registered under FIFRA Section 3 were cancelled in 2004 for failure to pay the required annual maintenance fee October 27, 2004, (69 FR 62666) (FRL 7683-7), but there are several FIFRA 24(c) Special Local Needs registrations (for weed control on mint) that are still active. Syngenta Crop Protection, Inc. has now requested cancellation of all of the remaining pyridate 24(c) registrations. The registrant's request will terminate the last pyridate products registered in the United States for these uses.

III. What Action is the Agency Taking?

This notice announces receipt by EPA of a request from a registrant to cancel all pyridate product registrations. The affected products and the registrant making the request are identified in Tables 1 and 2 of this unit.

Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that their pesticide registrations be canceled or amended to terminate one or more pesticide uses. Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30–day public comment period on the request for voluntary cancellation or use termination. In addition, section 6(f)(1)(C) of FIFRA requires that EPA provide a 180–day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

Because the pyridate registrant has not expressly waived the 180–day comment period, EPA will provide a 180–day comment period on the proposed requests.

Unless a request is withdrawn by the registrant within 180 days of publication of this notice, or if the Agency determines that there are substantive comments that warrant further review of this request, an order will be issued canceling the affected registrations.

TABLE 1.—PYRIDATE PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Company
CA010008	Tough 5EC	Syngenta Crop Protection, Inc.
ID010006	Tough 5EC	Syngenta Crop Protection, Inc.
IN010001	Tough 5EC	Syngenta Crop Protection, Inc.
MT010003	Tough 5EC	Syngenta Crop Protection, Inc.
ND000007	Tough 5EC	Syngenta Crop Protection, Inc.
OR010005	Tough 5EC	Syngenta Crop Protection, Inc.
WA010007	Tough 5EC	Syngenta Crop Protection, Inc.
*WI010005	Tough 5EC	Syngenta Crop Protection, Inc.

* Section 24c use in Wisconsin (WI010005) has expired and will not be reinstated.

Table 2 of this unit includes the name and address of record for the registrant of the products listed in Table 1 of this unit.

TABLE 2.—REGISTRANT REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
100	Syngenta Crop Protection, Inc. P.O. Box 18300 Greensboro, NC 27419-8300

IV. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

V. Procedures for Withdrawal of Request and Considerations for Reregistration of Pyridate

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**, postmarked before October 15, 2007. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. If this request for voluntary cancellation is granted, the Agency intends to issue a cancellation order that will allow persons other than the registrant to continue to use the FIFRA 24(c) labels to apply existing stocks of the previously-cancelled parent Section 3 product, Tough 5EC (EPA Reg. No. 100-880), to mint, provided such use is consistent with the 24(c) labels, until such existing stocks are exhausted. The registrant will not be permitted to sell or distribute the previously-cancelled parent Section 3 product, Tough 5EC (EPA Reg. No. 100-880), but existing stocks already in the hands of dealers or users may be distributed, sold or used legally until they are exhausted. If, as the Agency currently intends, the final cancellation order contains the existing stocks provision just described, the order will be sent only to the affected registrants of the cancelled products. If the Agency determines that the final cancellation order should contain existing stocks provisions different than the ones just described, the Agency will publish the cancellation order in the **Federal Register**.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: April 6, 2007.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E7–7258 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–507–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–0188; FRL–8123–7]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0188. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr.*

II. EUP

EPA has issued the following EUP:

72821–EUP–1. Extension. BHN Research, 16750 Bonita Beach Rd., Bonita Springs, FL 34135. This EUP allows the use of 0.306 pounds of the plant-incorporated protectant *Bacillus thuringiensis* subsp kurstaki Cry1A(c) in tomatoes on 500 acres of tomatoes. The program is authorized only in the States of California, Florida, Georgia, Illinois, Missouri, Puerto Rico, and Virginia. The EUP is effective from April 20, 2006 to April 20, 2007. A tolerance has been established for residues of the active ingredient in or on all food commodities.

Authority: 7 U.S.C. 136c.

List of Subjects

Environmental protection, Experimental use permits.

Dated: April 6, 2007.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. E7–7271 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–0326; FRL–8301–5]

Proposed Approval of the Central Characterization Project's Transuranic Waste Characterization Program at Los Alamos National Laboratory

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: The Environmental Protection Agency (EPA or we) is announcing the availability of, and soliciting public comments for 30 days on, the proposed approval of the radioactive, transuranic (TRU) waste characterization program implemented by the Central Characterization Project (CCP) at Los Alamos National Laboratory (LANL). This waste is intended for disposal at the Waste Isolation Pilot Plant (WIPP) in New Mexico. In accordance with the WIPP Compliance Criteria, EPA evaluated LANL–CCP's characterization of contact-handled TRU debris and solid waste during an inspection conducted May 23–25, 2006, as well as during follow-up inspections on August 22, 2006, and March 6, 2007. Using the systems and processes developed as part of the Department of Energy's (DOE's) Carlsbad Field Office (CBFO), EPA verified whether DOE could adequately characterize TRU waste consistent with the Compliance Criteria. The results of EPA's evaluation of the LANL–CCP program and the proposed approval are described in EPA's inspection report, which is available for review in the public dockets listed in **ADDRESSES**. We will consider public comments received on or before the due date mentioned in **DATES**.

This notice summarizes the waste characterization processes evaluated by EPA and EPA's proposed approval. As required by the 40 CFR 194.8, at the end of a 30-day comment period EPA will evaluate public comments received, finalize the report responding to the relevant public comments, and issue the final report and an approval letter to DOE's CBFO. Based on previous EPA inspections and approvals, LANL–CCP is currently approved to dispose of debris and solid waste at WIPP. LANL–CCP is permitted to continue waste characterization and disposal in accordance with prior site approvals while EPA establishes a baseline approval.

DATES: Comments must be received on or before May 18, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0326, by one of the following methods:

- *http://regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* to *a-and-r-docket@epa.gov*
- *Fax:* 202–566–1741
- *Mail:* Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Instructions: Direct your comments to Attn: Docket ID No. EPA–HQ–OAR–2007–0326. The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at *http://regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://regulations.gov* or e-mail. The *http://regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://regulations.gov*

your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://regulations.gov* or in hard copy at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742. These documents are also available for review in hard-copy form at the following three EPA WIPP informational docket locations in New Mexico: in Carlsbad at the Municipal Library, Hours: Monday–Thursday, 10 a.m.–9 p.m., Friday-Saturday, 10 a.m.–6 p.m., and Sunday, 1 p.m.–5 p.m., phone number: 505–885–0731; in Albuquerque at the Government Publications Department, Zimmerman Library, University of New Mexico, Hours: vary by semester, phone number: 505–277–2003; and in Santa Fe at the New Mexico State Library, Hours: Monday–Friday, 9 a.m.–5 p.m., phone number: 505–476–9700. As provided in EPA's regulations at 40 CFR Part 2, and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying.

FOR FURTHER INFORMATION CONTACT:

Rajani Joglekar, Radiation Protection Division, Center for Federal Regulations, Mail Code 6608J, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, Washington, DC 20460; telephone number: 202–343–9601; fax number: 202–343–2305; e-mail address: *joglekar.rajani@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. Background

DOE is developing the WIPP near Carlsbad in southeastern New Mexico as a deep geologic repository for disposal of TRU radioactive waste. As defined by the WIPP Land Withdrawal Act (LWA) of 1992 (Pub. L. 102–579), as amended (Pub. L. 104–201), TRU waste consists of materials containing processes having atomic numbers greater than 92 (with half-lives greater than twenty years), in concentrations greater than 100 nanocuries of alpha-emitting TRU isotopes per gram of waste. Much of the existing TRU waste consists of items contaminated during the production of nuclear weapons, such as rags, equipment, tools, and sludges.

On May 13, 1998, EPA announced its final compliance certification decision to the Secretary of Energy (published May 18, 1998, 63 FR 27354). This decision stated that the WIPP will comply with EPA's radioactive waste disposal regulations at 40 CFR Part 191, Subparts B and C.

The final WIPP certification decision includes conditions that (1) prohibit shipment of TRU waste for disposal at WIPP from any site other than the Los Alamos National Laboratories (LANL) until the EPA determines that the site has established and executed a quality assurance program, in accordance with §§ 194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5) for waste characterization activities and assumptions (Condition 2 of Appendix A to 40 CFR part 194); and (2) (with the exception of specific, limited waste streams and equipment at LANL) prohibit shipment of TRU waste for disposal at WIPP (from LANL or any other site) until EPA has approved the procedures developed to comply with the waste characterization requirements of § 194.22(c)(4) (Condition 3 of Appendix A to 40 CFR Part 194). The EPA's approval process for waste generator sites is described in § 194.8.

In July 2004, EPA promulgated changes to the ''Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with Disposal Regulations'' (69 FR 42571–42583, July 16, 2004). These changes went into effect October 14, 2004, which modified the EPA approval of waste characterization (''WC'') programs at DOE's TRU waste sites. These revisions provide equivalent or improved oversight and better prioritization of technical issues in EPA inspections to evaluate WC activities at DOE WIPP waste generator sites, and also offer more direct public input into the Agency's decisions about what waste can be disposed of at WIPP. They do not modify the technical approach that EPA has employed since the 1998 WIPP Certification Decision.

Condition 3 of the WIPP Certification Decision requires that EPA conduct independent inspections at DOE's waste generator/storage sites of their TRU

waste characterization capabilities before approving their program and the waste for disposal at the WIPP. The revised inspection and approval process gives EPA greater (a) discretion in establishing technical priorities, (b) ability to accommodate variation in the site's waste characterization capabilities, and (c) flexibility in scheduling site WC inspections. The § 194.8 changes require that EPA conduct a baseline inspection at every previously approved TRU site (such as AMWTP/INL). EPA expects that within two years after the effective date of October 2004 most of the previously approved TRU sites (such as Hanford, Los Alamos CCP, and Savannah River Site CCP) will undergo EPA baseline inspections. Following these inspections, the Agency will issue a new baseline compliance decision for these sites.

As part of the baseline inspection, EPA must evaluate each WC process component (equipment, procedures, and personnel training/experience) for its adequacy and appropriateness in characterizing TRU waste destined for the disposal at WIPP. During the inspection, the site demonstrates its capabilities to characterize TRU waste(s) and its ability to comply with the regulatory limits and tracking requirements under § 194.24. The baseline inspection can result in approval with limitations/conditions or may require follow-up inspection(s) before approval. The approval must specify what subsequent WC program changes or expansion should be reported to EPA. The Agency is required to assign Tier 1 (''TI'') and Tier 2 (''T2'') to the reportable changes depending on their potential impact on data quality. A T1 designation requires that the site must notify EPA of proposed changes to the approved components of an individual WC process (such as radioassay equipment or personnel), and EPA must also approve the change before it can be implemented. A WC element with a T2 designation allows the site to implement changes to the approved components of individual WC processes (such as visual examination procedures) but requires EPA notification. The Agency may choose to inspect the site to evaluate technical adequacy before approval. EPA inspections conducted to evaluate T1 or T2 changes are follow-up inspections under the authority of § 194.24(h). In addition to the follow-up inspections, if warranted, EPA may opt to conduct continued compliance inspections at TRU waste sites with a baseline approval under the authority of § 194.24(h).

The revisions to the site inspection and approval process outlined in § 194.8 require EPA to issue a **Federal Register** notice proposing the baseline compliance decision, docket the inspection report for public review, and seek public comment on the proposed decision for a period of 30 days. The report must describe the WC processes EPA inspected at the site, as well as their compliance with § 194.24 requirements.

III. Proposed Baseline Compliance Decision

In accordance with 40 CFR 194.8(b), EPA conducted a baseline inspection of the CCP's waste characterization program at LANL in Los Alamos, New Mexico. This inspection occurred on May 23–25, 2006, with a follow-up inspection of the visual examination (VE) process related to the sealed sources program conducted on August 22, 2006. On March 6, 2007, the Agency also performed an on-site follow-up evaluation at LANL to verify the resolution of all open EPA issues. (All three inspections are grouped under EPA Baseline Inspection No. LANL–CCP–05.06–8).

The CCP is a mobile characterization program that assists TRU waste generator sites with complex waste characterization activities. At some sites (such as LANL and Savannah River Site) and small TRU waste generator sites (such as Argonne National Laboratory and Lawrence Livermore National Laboratory) the CCP has the sole responsibility to characterize contact-handled (CH), retrievably-stored TRU waste destined for the disposal at the WIPP.

The purpose of EPA's inspection was to verify that LANL–CCP is characterizing CH TRU retrievably-stored debris waste (S5000) and solid waste (S3000), properly and in compliance with the regulatory requirements at 40 CFR 194.24. EPA also evaluated characterization of sealed sources collected and repackaged as part of the Offsite Source Recovery Program (OSRP) at LANL as a CH TRU newly-generated debris waste. During the inspection, EPA also evaluated LANL–CCP's use of the WIPP Waste Information System (WWIS) for tracking the contents of CH TRU waste containers destined for disposal at WIPP. This tracking ensures that the volume emplaced in the WIPP repository and characteristics of the emplaced wastes conform to the requirements of the WIPP LWA and the specific conditions of the WIPP Certification Decision.

During the inspection, EPA evaluated the adequacy, implementation, and effectiveness of LANL–CCP's waste characterization activities. The Agency's evaluation focused on the individual components—equipment, procedures, and personnel training/experience of the following waste characterization processes: Acceptable knowledge (AK), nondestructive assay (NDA), visual examination techniques (VET), visual examination/real-time radiography (VE/RTR), load management, and the WWIS. The overall program adequacy and effectiveness of LANL–CCP was based on the following DOE-provided upper-tier documents: (1) CCP–PO–001—Revision 13, 11/16/06—CCP Transuranic Waste Characterization Quality Assurance Project Plan and (2) CCP–PO–002—Revision 18, 11/16/06—CCP Transuranic Waste Certification Plan.

EPA previously evaluated and approved WC systems at LANL, most recently in April 2005 (EPA Docket No. A–98–49, II–A4–57). LANL received approval to dispose of contact handled, retrievably-stored debris (S5000) and solid waste (S3000), and repackaged sealed sources as newly-generated debris waste prior to this baseline inspection. The purpose of the LANL–CCP baseline and follow-up inspections was to evaluate the adequacy of the site's WC programs for two TRU waste categories—debris and solids—to be disposed of at the WIPP; the debris included sealed sources from the OSRP. During the inspections, the Agency examined the following activities:

- Acceptable knowledge (AK) and load management for contact-handled (CH) retrievably-stored TRU debris waste (S5000) and solid waste (S3000) and AK for CH newly-generated, repackaged debris waste from the OSRP.
- Visual examination (VE) as a quality control (QC) check of real-time radiography (RTR) and in lieu of RTR for CH retrievably-stored TRU debris waste (S5000) and solid waste (S3000) and Visual Examination Technique (VET) for CH newly-generated, repackaged debris waste from the OSRP.
- RTR for CH retrievably-stored TRU debris waste (S5000) and solid waste (S3000).
- Nondestructive assay (NDA), specifically, three NDA systems—LANL HENC #1 and LANL HENC #2 for characterizing debris (S5000) and solid (S3000) waste, respectively, and the portable tomographic gamma scanner

(PTGS) for characterizing debris waste (S5000) [1] only.

• WIPP Waste Information System (WWIS) for CH retrievably-stored TRU debris waste (S5000) and solid waste (S3000).

In addition to reviewing individual components (namely, procedures, and equipment) of each of the WC processes (AK, NDA, VET, VE/RTR, load management, and the WWIS), the Agency interviewed and reviewed training records of personnel responsible for compiling data, analyzing waste contents, operating equipment, and preparing data for WWIS tracking. EPA also required radioassay replicate analysis on selected containers from the population of previously analyzed waste containers on the same system or instrument for the two different waste categories. The purpose of this replicate testing is to provide EPA with an independent means to verify that the radioassay equipment being assessed for approval can provide consistent, reproducible results for the determination of the quantity of 10 WIPP-tracked radionuclides (241Am, 137Cs, 238Pu, 239Pu, 240Pu, 242Pu, 90Sr, 233U, 234U, and 238U) as well as TRU alpha concentration. The results of the replicate analysis help EPA to determine whether:

• The instrument produces results consistent with the reported total measurement uncertainty (TMU) by comparing the sample standard deviation for a number of replicate measurements taken over several hours or days to the reported TMU.

• The instrument provides reproducible results over longer periods of time, such as weeks or months, by comparing the results of the replicate measurement(s) to the original reported values.

The EPA inspection team identified one finding and seven concerns. The finding in the area of VE and five of the concerns required a response from DOE, while two concerns did not require a response. EPA Inspection Issue Tracking Forms (see Attachments C.1 through C.8 to the proposed baseline inspection report) document the finding and seven concerns. Personnel from LANL, CBFO, and CCP provided information on resolutions for the finding and concerns to the EPA inspection team prior to the closeout of the onsite inspection and after the inspection. The information provided by CBFO addressed the one finding and the concerns that required a response, as well as the two concerns that did not require a response. Between May 2006 and March 2007, CCP provided satisfactory resolution addressing three concerns while one finding and three concerns remained unresolved. At the follow-up inspection on March 6, 2007, CCP discussed with the EPA inspection team their responses for the four outstanding issues that EPA evaluated for completeness and adequacy, and concluded that each had been resolved satisfactorily. EPA considers the one finding and all concerns to be resolved, and there are no open issues resulting from this inspection.

The EPA inspection team determined that the LANL–CCP WC program activities were technically adequate. EPA is proposing to approve the LANL–CCP WC program in the configuration observed during this inspection and described in this report and the checklists included in the proposed baseline inspection report (Report Attachments A.1 through A.8). This proposed approval includes the following:

(1) The AK and load management process for CH retrievably-stored TRU debris and solid wastes and for newly-generated debris wastes from the OSRP.

(2) The LANL HENC #1 and LANL HENC #2 NDA systems for assaying solid and debris wastes.

(3) The PTGS NDA system for assaying debris waste.

(4) VE as a QC check of the RTR process and in lieu of the RTR process for retrievably-stored solid and debris wastes and VET of newly-generated debris wastes from the OSRP.

(5) The nondestructive examination process of RTR for retrievably-stored solid and debris wastes.

(6) The WWIS process for tracking of waste contents of solid and debris wastes, including debris from the OSRP.

LANL–CCP must report and, if applicable, receive EPA approval of any changes to the WC activities from the date of the baseline inspection, according to Table 1, below. Table 1 in this report is not identical to those included in previous baseline inspection reports and EPA site approval letters in several ways. The most important of these involve presentation of the Tier 2 (T2) elements. In previous reports there were two T2 columns that have been merged into a single T2 column for LANL–CCP. The T2 column entries have also been modified to better reflect the 40 CFR 194.24 (h) requirements that the site provide notification regarding the completion or availability of specific T2 elements, whereas the previous tables stated that the site must actually provide the T2 elements (document or procedure revisions, etc.). This approach is similar to the tiering tables used in EPA reports for sites characterizing remote handled TRU waste. Additionally, there are other minor word changes to the table for the sake of legibility.

There are changes to specific WC areas as well. For AK, the AK Reassessment Memoranda (reflecting resolution to concern LANL–CCP–AK–06–001CR) and the AK–VE Memoranda related to VE cited under T2 changes (reflecting resolution to finding LANL–CCP–VE–06–004F) do not appear in the tiering tables in previous baseline inspection reports. Similarly, requesting revisions to CCP–AK–008 or notification regarding the combination of waste streams that were distinct at the time of inspection are specific to the LANL OSRP or the result of information identified during this inspection. Accordingly, these are absent from the tiering tables in previous baseline inspection reports. For WWIS, changes to specific process elements (e.g., spreadsheets and data fields) are cited as T2 changes and these did not appear in previous tiering tables. These were added to provide a greater degree of specificity in an attempt to identify and focus on the key elements relevant to waste isolation.

The table below summarizes EPA's proposed tiering for LANL–CCP. As described previously, T1 changes require EPA approval prior to implementation of the change and may require EPA inspection to determine technical adequacy. T2 changes may be implemented prior to EPA approval; however, this type of change must be reported to EPA quarterly. Any changes to WC activities from the date of the baseline inspection must be reported to and, if applicable, approved by EPA, according to the following table:

[1] NDA systems are typically not matrix-specific in the same manner as other characterization techniques and their approval is not tied to specific waste matrix categories (i.e., S3000 or S5000). Specifically, virtually any material within the system's matrix calibration range may be assayed.

TABLE 1.—TIERING OF TRU WC PROCESSES IMPLEMENTED BY LANL–CCP BASED ON MAY 23–25, 2006 ON SITE BASELINE INSPECTION, AUGUST 22, 2006 OSRP INSPECTION AND MARCH 6, 2007 EVALUATION

WC process elements	LANL–CCP WC T1 changes	LANL–CCP WC T2 changes*
Acceptable Knowledge (AK) and Load Management.	Any new waste category, or new OSRP wastes addressed in AK Summaries separate from CCP–AK–008; AK (3), AK (6), AK (16) and (AK) 17. Implementation of Load Management for waste streams other than AK–009; AK (5).	Notification to EPA upon completion of AK Accuracy Reports; AK (2). Notification to EPA upon completion of updates to or substantive modifications of the following: —AK Reassessment Memoranda; AK (1) and AK (6). —AK–VE Memoranda related to VE and/or RTR techniques; AK (2). —AK–NDA Memoranda; AK (3). —Site procedures requiring CBFO approval; AK (4). —AK Summary CCP–AK–008, if changed to include newly approved ^{239}Pu and ^{241}Am sealed sources and/or irradiated sources; AK (6). —Combination of waste streams that were distinct at the time of this inspection; AK (6). —Change Notices used to modify and update WSPFs, including additions to waste stream(s) within an approved waste category; AK (9).
Nondestructive Assay (NDA)	New equipment or physical modifications to approved equipment**; NDA (1). Extension or changes to approved calibration range for approved equipment; NDA (2).	Notification to EPA upon completion of changes to software for approved equipment, operating range(s) and site procedures that require CBFO approval; NDA (2).
Real-Time Radiography (RTR)	N/A	Notification to EPA upon the following: —Implementation of new equipment or substantive changes to approved equipment; RTR (1). —Completion of changes to site procedures requiring CBFO approvals; RTR (2).
Visual Examination (VE) and Visual Examination Technique (VET), including OSRP Wastes (Sealed Source VET or SSVET).	N/A	Notification to EPA upon the following: —Completion of changes to site VE and VET procedures requiring CBFO approvals, including OSRP VET procedure; VE (1) and SSVET (1).
WIPP Waste Information System (WWIS)	N/A	Notification to EPA upon the following: —Completion of changes to WWIS procedure(s) requiring CBFO approvals; WWIS (1) and WWIS (2). —Changes to the Excel spreadsheet, WWIS data entry summary, characterization and certification; WWIS (1) and WWIS (2).

* Upon receiving EPA approval, LANL–CCP will report all T2 changes to EPA at the end of each fiscal year quarter.
** Modifications to approved equipment include all changes with the potential to affect NDA data relative to waste isolation and exclude minor changes, such as the addition of safety-related equipment.

EPA will notify the public of the results of its evaluations of proposed Tier 1 (T1) and T2 changes through postings to the EPA WIPP Web site and by sending e-mails to the WIPP-NEWS listserv (see Section 2.0 of this report for a brief discussion of tiering). All T1 changes must be submitted for evaluation and approval by EPA before their implementation. Upon approval, EPA will post the results of the evaluations through the EPA Web site and the WIPPNEWS list, as described above. Upon completion of its review of the T2 changes submitted at the end of each fiscal quarter, EPA will post the T2 changes. EPA expects the first report of LANL-CCP's T2 changes at the end of the fourth quarter FY 2007.

The scope of the site baseline compliance decision is based on EPA's inspections completed on May 25, 2006, and August 22, 2006, and the follow-up evaluation conducted on March 6, 2007.

IV. Availability of the Baseline Inspection Report for Public Comment

EPA has placed the report discussing the results of EPA's inspection of the CCP waste characterization program at LANL in the public docket as described in **ADDRESSES**. In accordance with 40 CFR 194.8, EPA is providing the public 30 days to comment on these documents. The Agency requests comments on the tiering designations and the proposed approval decision. EPA will accept public comment on this notice and supplemental information as described in Section 1.B. above. The EPA will not make a determination of compliance before the 30-day comment period ends. At the end of the public comment period, EPA will evaluate all relevant public comment and revise the inspection report as necessary. The Agency will then issue an approval letter and the final inspection report,

both of which will be posted on the WIPP Web site. The letter of approval will allow CCP to use the approved TRU waste characterization processes to characterize waste at LANL.

Information on the certification decision is filed in the official EPA Air Docket, Docket No. A–93–02 and is available for review in Washington, DC, and at the three EPA WIPP informational docket locations in New Mexico (as listed in **ADDRESSES**). The dockets in New Mexico contain only major items from the official Air Docket in Washington, DC, plus those documents added to the official Air Docket since the October 1992 enactment of the WIPP LWA.

Dated: April 11, 2007.

Elizabeth Cotsworth,

Director, Office of Radiation and Indoor Air.

[FR Doc. E7–7349 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

April 5, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before June 18, 2007. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: You may submit all your Paperwork Reduction Act (PRA) comments by e-mail or U.S. postal mail. To submit your comments by e-mail send them to *PRA@fcc.gov.* To submit your comments by U.S. mail, mark them to the attention of Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 and to Jasmeet Seehra, Office of Management and Budget, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to *Jasmeet_K._Seehra@omb.eop.gov* or via fax at (202) 395–5167.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection(s) send an e-mail to *PRA@fcc.gov* or contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0700.

Title: Open Video Systems Provisions.

Form Number: FCC 1275.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; State, local or tribal government.

Number of Respondents: 270.

Estimated Time per Response: 0.25 to 20 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 9,880 hours.

Total Annual Cost: None.

Nature of Response: Required to obtain or retain benefits.

Confidentiality: No need for confidentiality required.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Section 302 of the 1996 Telecommunications Act provides for specific entry options for telephone companies wishing to enter the video programming marketplace, one option being to provide cable service over an ''open video system'' (''OVS'').

47 CFR 76.1502(a) states an operator of an open video system must certify to the Commission that it will comply with the Commission's regulations in 47 CFR 76.1503, 76.1504, 76.1506(m), 76.1508, 76.1509, and 76.1513. The Commission must approve such certification prior to the commencement of service at such a point in time that would allow the applicant sufficient time to comply with the Commission's notification requirements.

(b) Certifications must be verified by an officer or director of the applicant, stating that, to the best of his or her information and belief, the representations made therein are accurate.

(c) Certifications must be filed on FCC Form 1275 and must include:

(1) The applicant's name, address and telephone number;

(2) A statement of ownership, including all affiliated entities;

(3) If the applicant is a cable operator applying for certification in its cable franchise area, a statement that the applicant is qualified to operate an open video system under Section 76.1501.

(4) A statement that the applicant agrees to comply and to remain in compliance with each of the Commission's regulations in §§ 76.1503, 76.1504, 76.1506(m), 76.1508, 76.1509, and 76.1513;

(5) If the applicant is required under 47 CFR 64.903(a) of this chapter to file a cost allocation manual, a statement that the applicant will file changes to its manual at least 60 days before the commencement of service;

(6) A list of the names of the anticipated local communities to be served upon completion of the system;

(7) The anticipated amount and type (i.e., analog or digital) of capacity (for switched digital systems, the anticipated number of available channel input ports); and

(8) A statement that the applicant will comply with the Commission's notice and enrollment requirements for unaffiliated video programming providers.

(d)(1) On or before the date an FCC Form 1275 is filed with the Commission, the applicant must serve a copy of its filing on all local communities identified pursuant to paragraph (c)(6) of this section and must include a statement informing the local communities of the Commission's requirements in paragraph (e) of this section for filing oppositions and comments. Service by mail is complete upon mailing, but if mailed, the served documents must be postmarked at least 3 days prior to the filing of the FCC Form 1275 with the Commission.

(2) Parties are required to attach a cover sheet to the filing indicating that the submission is an open video system certification application. The only wording on this cover sheet shall be ''Open Video System Certification Application'' and ''Attention: Media Bureau.'' This wording shall be located in the center of the page and should be

in letters at least ½ inch in size. Parties shall also include the words ''open video systems'' on their mailing envelope.

(e)(1) Comments or oppositions to a certification must be filed within five calendar days of the Commission's receipt of the certification and must be served on the party that filed the certification. If, after making the necessary calculations, the due date for filing comments falls on a holiday, comments shall be filed on the next business day before noon, unless the nearest business day precedes the fifth calendar day following a filing, in which case the comments will be due on the preceding business day. For example, if the fifth day falls on a Saturday, then the filing would be due on that preceding Friday. However, if the fifth day falls on Sunday, then the filing will be due on the next day, Monday, before noon (or Tuesday, before noon if the Monday is a holiday).

(2) Parties wishing to respond to a FCC Form 1275 filing must submit comments or oppositions with the Office of the Secretary and the Bureau Chief, Media Bureau. Comments will not be considered properly filed unless filed with both of these Offices. Parties are required to attach a cover sheet to the filing indicating that the submission is a pleading related to an open video system application, the only wording on this cover sheet shall be ''Open Video System Certification Application Comments.'' This wording shall be located in the center of the page and should be in letters at least ½ inch in size. Parties shall also include the words ''open video systems'' on their mailing envelopes.

(f) If the Commission does not disapprove the certification application within ten days after receipt of an applicant's request, the certification application will be deemed approved. If disapproved, the applicant may file a revised certification or refile its original submission with a statement addressing the issues in dispute. Such refilings must be served on any objecting party or parties and on all local communities in which the applicant intends to operate. The Commission will consider any revised or refiled FCC Form 1275 to be a new proceeding and any party who filed comments regarding the original FCC Form 1275 will have to refile their original comments if they think such comments should be considered in the subsequent proceeding.

47 CFR 76.1503(b)(1) states an open video system operator shall file with the Secretary of the Federal Communications Commission a ''Notice of Intent'' to establish an open video system, which the Commission will release in a Public Notice. Parties are required to attach a cover sheet to the filing indicating that the submission is an Open Video System Notice of Intent. The only wording on this cover sheet shall be ''Open Video System Notice of Intent'' and ''Attention: Media Bureau.'' This wording shall be located in the center of the page and should be in letters at least ½ inch in size. Parties shall also include the words ''open video systems'' on their mailing envelopes. Parties must submit copies of the Notice of Intent with the Office of the Secretary and the Bureau Chief, Media Bureau. The Notice of Intent shall include the following information:

(i) A heading clearly indicating that the document is a Notice of Intent to establish an open video system;

(ii) The name, address and telephone number of the open video system operator;

(iii) A description of the system's projected service area;

(iv) A description of the system's projected channel capacity, in terms of analog, digital and other type(s) of capacity upon activation of the system;

(v) A description of the steps a potential video programming provider must follow to seek carriage on the open video system, including the name, address and telephone number of a person to contact for further information;

(vi) The starting and ending dates of the initial enrollment period for video programming providers;

(vii) The process for allocating the system's channel capacity, in the event that demand for carriage on the system exceeds the system's capacity; and

(viii) A certification that the operator has complied with all relevant notification requirements under the Commission's open video system regulations concerning must-carry and retransmission consent (§ 76.1506), including a list of all local commercial and non-commercial television stations served, and a certificate of service showing that the Notice of Intent has been served on all local cable franchising authorities entitled to establish requirements concerning the designation of channels for public, educational and governmental use.

(2) Information. An open video system operator shall provide the following information to a video programming provider within five business days of receiving a written request from the provider, unless otherwise included in the Notice of Intent:

(i) The projected activation date of the open video system. If a system is to be activated in stages, the operator should describe the respective stages and the projected dates on which each stage will be activated;

(ii) A preliminary carriage rate estimate;

(iii) The information a video programming provider will be required to provide to qualify as a video programming provider, e.g., creditworthiness;

(iv) Technical information that is reasonably necessary for potential video programming providers to assess whether to seek capacity on the open video system, including what type of customer premises equipment subscribers will need to receive service;

(v) Any transmission or reception equipment needed by a video programming provider to interface successfully with the open video system; and

(vi) The equipment available to facilitate the carriage of unaffiliated video programming and the electronic form(s) that will be accepted for processing and subsequent transmission through the system.

47 CFR 76.1504(d) states complaints regarding rates shall be limited to video programming providers that have sought carriage on the open video system. If a video programming provider files a complaint against an open video system operator meeting the above just and reasonable rate presumption, the burden of proof will rest with the complainant. If a complaint is filed against an open video system operator that does not meet the just and reasonable rate presumption, the open video system operator will bear the burden of proof to demonstrate, using the principles set forth below, that the carriage rates subject to the complaint are just and reasonable.

47 CFR 76.1506(l)(2) states must-carry/retransmission consent election notifications shall be sent to the open video system operator. An open video system operator shall make all must-carry/retransmission consent election notifications received available to the appropriate programming providers on its system.

(3) Television broadcast stations are required to make the same election for open video systems and cable systems serving the same geographic area, unless the overlapping open video system is unable to deliver appropriate signals in conformance with the broadcast station's elections for all cable systems serving the same geographic area.

(4) An open video system commencing new operations shall notify all local commercial and noncommercial broadcast stations as

required under paragraph (l) of this section on or before the date on which it files with the Commission its Notice of Intent to establish an open video system.

47 CFR 76.1508(c) states any provision of § 76.94 that refers to a ''cable system operator'' or ''cable television system operator'' shall apply to an open video system operator. Any provision of § 76.94 that refers to a ''cable system'' or ''cable television system'' shall apply to an open video system except § 76.94 (e) and (f) which shall apply to an open video system operator. Open video system operators shall make all notifications and information regarding the exercise of network non-duplication rights immediately available to all appropriate video programming provider on the system. An open video system operator shall not be subject to sanctions for any violation of these rules by an unaffiliated program supplier if the operator provided proper notices to the program supplier and subsequently took prompt steps to stop the distribution of the infringing program once it was notified of a violation.

47 CFR 76.1509(c) states any provision of § 76.155 that refers to a ''cable system operator'' or ''cable television system operator'' shall apply to an open video system operator. Any provision of § 76.155 that refers to a ''cable system'' or ''cable television system'' shall apply to an open video system except § 76.155(c) which shall apply to an open video system operator. Open video system operators shall make all notifications and information regarding exercise of syndicated program exclusivity rights immediately available to all appropriate video programming provider on the system. An open video system operator shall not be subject to sanctions for any violation of these rules by an unaffiliated program supplier if the operator provided proper notices to the program supplier and subsequently took prompt steps to stop the distribution of the infringing program once it was notified of a violation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E7–7290 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collections Being Submitted for Review to the Office of Management and Budget

April 12, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collections, as required by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a current valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid control number. Comments are requested concerning: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written PRA comments should be submitted on or before May 18, 2007. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Jasmeet Seehra, Office of Mangement and Budget (OMB), Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503, or via fax at (202) 395–5167 or via Internet at *Jasmeet_K._Seehra@omb.eop.gov*, and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *PRA@fcc.gov.* If you would like to obtain or view a copy of this information collection, you may do so by visiting the FCC's PRA Web page at: *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918 or via the Internet at *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1053.

Title: 47 CFR Sections 64.604 and 64.605—Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; IP Captioned Telephone Service, Declaratory Ruling, CG Docket No. 03–123.

Form Number: Not Applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 6.

Estimated Time per Response: 8 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 96 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personal identifiable information (PII) from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On August 1, 2003, the Commission released the *Declaratory Ruling,* In the Matter of Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CC 98–67, FCC 03–190. In the *Declaratory Ruling,* the Commission clarified that one-line captioned telephone voice carry over (VCO) service is a type of telecommunications relay service (TRS) and that eligible providers of such services are eligible to recover their costs in accordance with section 225 of the Communications Act. The Commission also clarified that certain TRS mandatory minimum standards does not apply to one-line captioned VCO service, and waived 47 CFR 64.604(a)(1) and (a)(3) of the Commission's rules for all current and future captioned telephone VCO service providers, for the same period of time beginning August 1, 2003. The waivers were contingent on the filing of annual reports, for a period of three years, with the Commission. Sections 64.604(a)(1) and (a)(3) of the Commission's rules, which contained information collection requirements under the PRA became effective on March 26, 2004.

On July 19, 2005, the Commission released an *Order,* In the Matter of Telecommunication Relay Services and Speech-to-Speech Services for

Individuals with Hearing and Speech Disabilities, CC 98–67 and CG Docket No. 03–123, FCC 05–141, that clarified two-line captioned telephone VCO service, like one-line captioned telephone VCO service, is a type of TRS eligible for compensation from the Interstate TRS Fund. Also, the Commission clarified that certain TRS mandatory minimum standards do not apply to two-line captioned VCO service, and waived 47 CFR 64.604(a)(1) and (a)(3) of the Commission's rules, for providers who offers two-line captioned VCO service. This clarification increased the number of providers who will be providing one-line and two-line captioned VCO services.

On January 11, 2007, the Commission released a *Declaratory Ruling,* In the Matter of Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123, FCC 06–182, granting a request for clarification that Internet Protocol (IP) captioned telephone relay service (IP CTS) is a type of TRS eligible for compensation from the Interstate TRS Fund when offered in compliance with the applicable TRS mandatory minimum standards.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E7–7295 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 03–123; DA 07–1396]

The Federal Communications Commission's Policies and Practices Under Section 504 of the Rehabilitation Act of 1973

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission initiates review of its policies and practices under Section 504 of the Rehabilitation Act of 1973 (*Section 504 Handbook*). By doing so, the Commission seeks comment on the accessibility of its programs and activities. The Commission's rules mandate that it conduct a review of its current policies and practices in view of advances in relevant technology and achievability every three years.

DATES: Comments are due on or before May 22, 2007.

ADDRESSES: You may submit comments identified by CG Docket No. 03–123, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Parties who choose to file by paper should also submit their comments on diskette. These diskettes should be submitted, along with three paper copies to Diane Mason, Consumer & Governmental Affairs Bureau, Disability Rights Office, 445 12th Street, SW., Room 3–C418, Washington, DC 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM compatible formatted using Word 97 or compatible software. The diskette should be accompanied by a cover letter and should be submitted in ''read only'' mode. The diskette should be clearly labeled with the commenter's name, proceeding (including the lead docket number in this case (CG Docket No. 03–123)), type of pleading (comment or reply comment), date of submission, and the name of the electronic file on the diskette. The label should also include the following phrase ''Disk Copy—Not an Original.'' Each diskette should contain only one party's pleadings, preferably in a single electronic file. In addition, commenters must send diskette copies to the Commission's contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone (202) 418–0539 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Diane Mason, (202) 418–7126 (voice), (202) 418–7828 (TTY), or e-mail *Diane.Mason@fcc.gov.*

SUPPLEMENTARY INFORMATION: On March 12, 2003, the Commission released *Amendment of Part 1, Subpart N of the Commission's Rules Concerning Non-Discrimination on the Basis of Disability in the Commission's Programs and Activities,* Order, FCC 03–48, which published in the **Federal Register** at 68 FR 22315, April 28, 2003, effectuating Section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amend Section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of disability in programs or activities conducted by Executive agencies or the United States Postal Service. This is a summary of the Commission's document DA 07–1396, released March 23, 2007. Pursuant to §§ 1.415 and 1.419 of the Commission rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998.

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Filers should follow the instructions provided on the Web site for submitting comments.
- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov*, and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response. All comments received are viewable by the general public at any time through the Web site.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

The full text of document DA 07–1396 and copies of any subsequently filed documents relating to this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. Document DA 07–1396 and copies of subsequently filed documents in this matter may also be purchased from the Commission's contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact the Commission's contractor at their Web site *http://www.bcpiweb.com* or by calling 1–800–378–3160.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY). Document DA 07–1396 can also be downloaded in Word and Portable Document Format (PDF) at *http://www.fcc.gov/cgb.dro*.

Synopsis

The Commission seeks comment on the overall accessibility of its activities and programs. This includes, but is not limited to, the availability of sign language interpreters, physically accessible buildings and meeting spaces, Braille documents, assistive listening devices, Communication Access Realtime Translation (CART), captioning, and other forms of reasonable accommodation for access to its programs and activities. The Commission furthers seeks comment on the procedures set forth in the *Section 504 Handbook*.

Federal Communications Commission.

Jay Keithley,

Deputy Bureau Chief, Consumer & Governmental Affairs Bureau.

Appendix A–47 CFR 1.1810. Review of Compliance

(a) The Commission shall, beginning in 2004 and at least every three years thereafter, review its current policies and practices in view of advances in relevant technology and achievability. Based on this review, the Commission shall modify its practices and procedures to ensure that the Commission's programs and activities are fully accessible.

(b) The Commission shall provide an opportunity to interested persons, including individuals with disabilities or organizations representing individuals with disabilities, to participate in the review process by submitting comments. Written comments shall be signed by the commenter or by someone authorized to do so on his or her behalf. The signature of the commenter, or signature of someone authorized by the commenter to do so on his or her behalf, shall be provided on print comments. Comments in audio, Braille, electronic, and/or video formats shall contain an affirmative identity statement of the individual, which for this purpose shall be considered to be functionally equivalent to a commenter's signature.

(c) The Commission shall maintain on file and make available for public inspection for four years following completion of the compliance review—

(1) A description of areas examined and problems identified;

(2) All comments and complaints filed regarding the Commission's compliance; and

(3) A description of any modifications made.

Appendix B–47 CFR 1.1805. Federal Communications Commission Section 504 Programs and Activities Accessibility Handbook

The Consumer & Governmental Affairs Bureau shall publish a ''Federal Communications Commission Section 504 Programs and Activities Accessibility Handbook'' (''Section 504 Handbook'') for Commission staff, and shall update the Section 504 Handbook as necessary and at least every three years. The Section 504 Handbook shall be available to the public in hard copy upon request and electronically on the Web site. The Section 504 Handbook shall contain procedures for releasing documents, holding meeting, receiving comments, and for other aspects of Commission programs and activities to achieve accessibility. These procedures will ensure that the Commission presents a consistent and complete accommodation policy pursuant to 29 U.S.C. 794, as amended. The Section 504 Handbook is for internal staff use and public information only, and is not intended to create any rights, responsibilities, or independent cause of action against the Federal Government.

[FR Doc. E7–7256 Filed 4–17–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's Office of Agreements (202–523–5793 or *tradeanalysis@fmc.gov*).

Agreement No.: 011733–021.

Title: Common Ocean Carrier Platform Agreement.

Parties: A.P. Moller-Maersk A/S; CMA CGM; Hamburg-Süd; Hapag-Lloyd AG; Mediterranean Shipping Company S.A.; and United Arab Shipping Company (S.A.G.) as shareholder parties, and Alianca Navegacao e Logistica Ltda.; Compania Sud Americana de Vapores, S.A.; Companhia Libra de Navegacao; Emirates Shipping Lines; Hyundai Merchant Marine Co. Ltd; Kawasaki Kisen Kaisha, Ltd.; MISC Berhad; Mitsui O.S.K. lines Ltd.; Nippon Yusen Kaisha; Safmarine Container Lines N.V.; Senator Lines GmbH; Norasia Container Lines Limited; and Tasman Orient Line C.V. as non-shareholder parties.

Filing Party: Wayne R. Rohde, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The amendment adds COSCO Container Lines Co., Ltd. as a non-shareholder party to the agreement.

Agreement No.: 011994.

Title: Maersk Line/HSDG Space Charter Agreement.

Parties: A.P. Moller Maersk A/S and Hamburg Süd.

Filing Party: Wayne R. Rohde, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The agreement authorizes Maersk Line to charter space to Hamburg Süd on a short term basis from North Europe to the U.S. East Coast.

Agreement No.: 011995.

Title: Maersk Line/ELJSA Slot Exchange Agreement.

Parties: A.P. Moller Maersk A/S and the Evergreen Line Joint Service Agreement.

Filing Party: Wayne R. Rohde, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The agreement authorizes the parties to exchange slots in the trade between North China and Japan, on the one hand, and California, on the other.

By Order of the Federal Maritime Commission.

Dated: April 13, 2007.

Bryant L. VanBrakle,

Secretary.

[FR Doc. E7–7356 Filed 4–17–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR Part 515, effective on the corresponding date shown below:

License Number: 018938F.
Name: Carex Shipping, LLC.
Address: 2235 E. Flamingo, Ste. 201G, Las Vegas, NV 89119.
Date Revoked: April 5, 2007.
Reason: Surrendered license voluntarily.

License Number: 012286N.
Name: Condor Seaway, Inc.
Address: 10975 NW 29th Street, Miami, FL 33172.
Date Revoked: March 25, 2007.
Reason: Failed to maintain a valid bond.

License Number: 017121N.
Name: Freight Logistics Services, LLC.
Address: 21905 64th Avenue West, Ste. 301–A, Mountlake Terrace, WA 98043.
Date Revoked: March 24, 2007.
Reason: Failed to maintain a valid bond.

License Number: 018562F.
Name: Global Tassili Transport Services, Inc.
Address: 8206 Fairbanks North Houston, Houston, TX 77064.
Date Revoked: March 29, 2007.
Reason: Failed to maintain a valid bond.

License Number: 002402F.
Name: Robert Gage Marshall dba Robert G. Marshall, CHB.
Address: 204 South Lane Avenue, Jacksonville, FL 32254.
Date Revoked: April 1, 2007.
Reason: Failed to maintain a valid bond.

License Number: 012382N.
Name: Sea Systems Ocean Line, Inc.
Address: 545 Hanover Park W., Ste. 109, Tukwila, WA 98188.
Date Revoked: March 23, 2007.
Reason: Failed to maintain a valid bond.

License Number: 018851NF.
Name: Sembcorp Logistics (USA) Inc.
Address: 815–817 West Arbor Vitae Street, Inglewood, CA 90301.
Date Revoked: March 27, 2007.
Reason: Surrendered license voluntarily.

License Number: 001849F.
Name: Stiegler Shipping Company, Inc.
Address: 1151 Hillcrest Road, Ste. F, Mobile, AL 36695.
Date Revoked: April 2, 2007.
Reason: Failed to maintain a valid bond.

License Number: 004395N.
Name: Superior Link International Inc.
Address: 380 S. Lemon Avenue, Ste. G, Walnut, CA 91789.
Date Revoked: April 1, 2007.
Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. E7–7353 Filed 4–17–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder-Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel-Operating Common Carrier Ocean Transportation Intermediary Applicants

Clarion Logistics USA, Inc., 208 NE Alice Street, Jensen Beach, FL 34957. *Officers:* Michael Gabbett, Vice President, (Qualifying Individual), Rod Miller, President.

Universe Express Inc., 39–06 Ackerman Drive, Fair Lawn, NJ 07410. *Officers:* Yecenia Blanco, Corporate Secretary, (Qualifying Individual), Eytan Shaya, CEO.

Yishun Logistics (USA) Inc., 103 Mott Street, Suite 207, New York, NY 10013. *Officers:* Chun Hua Pan, Vice President, (Qualifying Individual), Li Jun Wang, President.

SR Intel Freight, Inc., 1999 W. Walnut Street, Compton, CA 90220. *Officers:* Wu J. Yi, Secretary, (Qualifying Individual), Steven Park, President.

Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicant

New World Forwarding LLC, 8524 Hwy. 6 North #276, Houston, TX 77095. *Officers:* Eric Peterson, General Manager, (Qualifying Individual), Sherry Peterson, Vice President.

Ocean Freight Forwarder-Ocean Transportation Intermediary Applicant

Global Connection Logistics, Inc., 3650 NW 115th Avenue, Miami, FL 33178. *Officer:* Claudia Maniero, President, (Qualifying Individual.)

Dated: April 13, 2007.

Bryant L. VanBrakle,

Secretary.

[FR Doc. E7–7355 Filed 4–17–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409), and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
017126N	Daily Freight Cargo, Corp., 8538 NW 70th Street, Miami, FL 33166	January 19, 2007.
017121F	Freight Logistics Services, LLC, 21905 64th Avenue West, Suite 301–A, Mountlake Terrace, WA 98043.	March 24, 2007.
018123F	Susie Gonzalez, Inc. dba F.R.I.E.N.D.S. Cargo Int'l, 8367 NW 74th Street, Miami, FL 33166	March 2, 2007.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. E7–7354 Filed 4–17–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices, Acquisition of Shares of Bank or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. E7-6987) published on pages 18655-18656 of the issue for Friday, April 13, 2007.

Under the Federal Reserve Bank of St. Louis heading, the entry for Rebecca Mason Irvine, Louisville, Kentucky, and others, is revised to read as follows:

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. Rebecca Mason Irvine, Louisville, Kentucky, James Edward Mason, Elizabethtown, Kentucky, and Deborah Mason Garner, New Albany, Indiana, as a group acting in concert, and Darrell Richard Wells, Louisville, Kentucky, to acquire control of Magnolia Bancshares, Inc., Hodgenville, Kentucky, and thereby indirectly acquire control of Bank of Magnolia, Magnolia, Kentucky.

Comments on this application must be received by April 27, 2007.

Board of Governors of the Federal Reserve System, April 13, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–7326 Filed 4–17–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 14, 2007.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. The Farmers State Bank of Fort Morgan, Colorado Employee Stock Ownership Plan, to acquire up to 38 percent of the voting shares of F.S.B. Bancorporation of Fort Morgan, Colorado, and thereby indirectly acquire voting shares of Farmers State Bank of Fort Morgan, all in Fort Morgan, Colorado.

Board of Governors of the Federal Reserve System, April 13, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–7325 Filed 4–17–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of March 20–21, 2007

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on March 20–21, 2007.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long–run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with maintaining the federal funds rate at an average of around 5¼ percent.

By order of the Federal Open Market Committee, April 12, 2007.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. 07–1942 Field 4–16–07; 1:46 pm]

BILLING CODE 6210–01–S

[1] Copies of the Minutes of the Federal Open Market Committee meeting on March 20–21, 2007, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The FTC is submitting the information collection requirements described below to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC is seeking public comments on proposed information requests to food and beverage companies and quick service restaurants. The FTC proposes to issue compulsory process orders to major food and beverage manufacturers, distributors, and marketers and quick service restaurant companies for information concerning, among other things, their marketing activities and expenditures targeted toward children and adolescents.

DATES: Comments must be filed on or before May 18, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to the ''Food Industry Marketing to Children Report: Paperwork Comment; FTC File No. P064504'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission/ Office of the Secretary, Room H–135 (Annex J), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as prescribed below. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document

must be clearly labeled ''Confidential.''[1] The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible.

Comments filed in electronic form should be submitted by using the following weblink: *https://secure.commentworks.com/foodmarketingpaperworkcomment* (and following the instructions on the Web-based form). To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at the weblink *https://secure.commentworks.com/foodmarketingpaperworkcomment.* If this notice appears at *http://www.regulations.gov,* you may also file an electronic comment through that Web site. The Commission will consider all comments that regulations.gov forwards to it.

Comments should also be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395–6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The Federal Trade Commission Act, 15 U.S.C. 42–58 (FTC Act), and other laws the Commission administers permit the collection of public comments to consider and use as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Carol Jennings, (202) 326–3010, or Sarah Botha, (202) 326–2036, Attorneys, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission. The FTC staff contacts can be reached by mail at: Federal Trade Commission, 600 Pennsylvania Avenue, NW., NJ–3212, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On November 22, 2005, the President signed a bill appropriating funds for the Commission for FY 2006. Public Law No. 109–108. The Conference Report (H.R. Rep. No. 109–272 (2005)) for this law incorporates by reference language from the Senate Report (S. Rep. No. 109–88 (2005)), instructing the FTC to prepare a report on food industry marketing activities and expenditures targeted to children and adolescents.[2] To prepare the report, the Commission needs relevant information, including empirical data, on the nature and extent of marketing activities and expenditures targeted to children and adolescents.

On March 1, 2006, the FTC published a notice in the **Federal Register** requesting relevant information. 71 FR 10535. In response, the Commission received comments from five food industry associations, two public health advocacy organizations, a marketing trade organization, and one individual.[3] In general, the comments suggested resources from which relevant information may be available and points to consider in developing the report. However, the comments presented minimal information, especially empirical data, on the nature and extent of marketing activities and expenditures targeted to children and adolescents. The Commission thus requires additional data and information in order to prepare the report.

The FTC has the authority to compel production of these data and information from food and beverage manufacturers, distributors, and marketers and quick service restaurant companies (''industry members'') under Section 6(b) of the FTC Act, 15 U.S.C. 46(b). The Commission intends to send its information requests to the ultimate parents of these types of companies to assure that no relevant data from affiliated or subsidiary companies goes unreported. Because the number of separately incorporated companies affected by the Commission's requests will exceed nine entities, the Commission seeks OMB clearance under the PRA, 44 U.S.C. 3501–3520.

Under the PRA, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. As required by the PRA, the FTC published a **Federal Register** Notice on October 23, 2006 seeking comments from the public concerning the proposed collection of information from food and beverage companies and quick service restaurants. *See* 71 FR 62109 (October 23 Notice). As discussed below, twenty-seven comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR part 1320), the FTC is providing this second opportunity for public comment while requesting that OMB grant the clearance for the proposed collection of information. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before May 18, 2007.

A. Public Comments

The FTC received twenty-seven comments in response to the October 23 Notice.[4] Sixteen of the comments were filed by one organization, and did not specifically address the proposed data collection.[5] Eight of the comments expressly favored the proposed data collection. These were submitted by: (1) the Public Health Institute (PHI) and, separately, the Public Health Law Program (PHLP) of the PHI; (2) members of the Children's Media Policy Coalition of the Georgetown University Law Center Institute for Public Representation (CMPC members);[6] (3) Consumers Union; (4) the California Department of Health Services (CDHS); and (5) three individual consumers, including one nutrition educator. The remaining three comments did not oppose the data collection but made suggestions for enhancing the quality, utility, and clarity of the information to be collected and for reducing the burden on the companies. These came from the Mercatus Center at George Mason University, food and beverage industry member Burger King Corporation (BKC), and the Grocery Manufacturers

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] The Senate Report requests that the FTC's report: Include an analysis of commercial advertising time on television, radio, and in print media; in-store marketing; direct payments for preferential shelf placement; events; promotions on packaging; all Internet activities; and product placements in television shows, movies, and video games.

[3] The comments are available at *http://www.ftc.gov/os/comments/foodmarketingstudy/index.htm.*

[4] The comments are available at *http://www.ftc.gov/os/comments/foodmktgtokids-pra/index.htm.*

[5] The sixteen comments were filed by the Loyola of Los Angeles Law Review and consisted of sixteen articles published in the Law Review in conjunction with a symposium held at Loyola Law School on October 21, 2005 on ''Food Marketing to Children and the Law.'' *See* Comments by Loyola of Los Angeles Law Review (Nov. 16, 2006).

[6] Specifically, a comment was submitted by the following members of the Children's Media Policy Coalition: Action Coalition for Media Education, Benton Foundation, Children Now, National PTA, and the Office of Communication of the United Church of Christ, Inc.

Association and Food Products Association (GMA/FPA).

1. General Support for the Data Collection

The Consumers Union comment stated that the proposed information collection is essential to the FTC fulfilling its consumer protection mandate and to enabling the FTC to provide key information for Congress and to meet the recommendation of the Institute of Medicine of the National Academies (IOM) to report on the status of food and beverage marketing to children. Consumers Union further noted that the information collection could provide a basis for sound policy-making in the area of food and beverage marketing to children and adolescents. The CDHS comment stated that the FTC's report, which will be based on information collected in response to the proposed Section 6(b) Orders, will guide the CDHS's own program planning, intervention and evaluation, and counter-advertising. CDHS stated that the report would also level the playing field among industry competitors by requiring all companies to disclose their marketing practices and, if necessary, would guide the development of state or federal regulatory and enforcement actions for food marketing to children.

One individual consumer commented that the information collection process is essential to making any determinations about what government action may be needed in the area of food and beverage marketing to children.[7] Another consumer similarly stated that the proposed Section 6(b) Orders are necessary for the government to take appropriate action in the debate regarding food marketing to children.[8]

2. Utility of the Information Collection

In its October 23 Notice, the FTC stated that it would seek relevant information, including empirical data, on the nature and extent of marketing activities and expenditures targeted to children and adolescents. The FTC invited comments on whether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility. The Mercatus Center commented that, given the recent action by the Children's Advertising Review Unit (CARU) to update its self-regulatory guidelines as well as the Better Business Bureau's (BBB) Children's Food and Beverage Advertising Initiative entered into by eleven major marketers of food and beverage products to children, the data requested in the proposed Section 6(b) Orders may be outdated. The Mercatus Center suggested that the FTC request copies of new marketing plans that would reflect any changes resulting from the recent CARU and BBB initiatives. The FTC agrees that any new corporate policies and initiatives will enable the agency to report on any planned changes in the food and beverage industry's practices in marketing to children, and will request copies of such policies and initiatives in the proposed Section 6(b) Orders. However, information on recent expenditures and activities will allow the agency to present a complete and relatively current picture of marketing expenditures and activities targeted to children as well as adolescents—which are not covered by the CARU and BBB initiatives, and will serve as a benchmark for any future measurements of food and beverage marketing to children and adolescents. As a result, the proposed information requests will also seek these data.

Consumers Union strongly supported the FTC's proposal to request information on advertising expenditures and activities in both measured and unmeasured media. Consumers Union noted that use of unmeasured media is on the rise and that collection of these data will allow the FTC to provide a full picture of the marketing of food products to children and adolescents. The CDHS comment stated that the proposed information collection is necessary to determine the degree to which self-regulatory programs and other voluntary marketing restrictions are being implemented.

The GMA/FPA stated that the need for data is limited when compared to the cost of obtaining and compiling it, and noted that food and beverage television advertising to children has substantially decreased over the last thirty years and is not likely a factor that contributes to increasing childhood obesity levels. BKC suggested that the FTC limit the scope and substance of the information requests and the report to focus on empirical data relating to advertising expenditures and practices. BKC noted that Congress has not asked the agency to study the link between advertising and obesity. The proposed Section 6(b) Orders and the FTC's forthcoming report will address marketing activities and expenditures by the food and beverage industry that are targeted to children and adolescents; the Orders and report will not attempt to analyze any purported causal connection between advertising and obesity, as this subject is outside the scope of the report Congress requested. However, Congress expressly requested that the report address expenditures and activities in both measured and unmeasured media categories, and the FTC requires empirical data from industry members to do so.

3. Accuracy of Estimated Burden of the Information Collection

In the October 23 Notice, the FTC invited comments on the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used. The GMA/FPA stated that, while the aggregate costs of complying with the proposed data requests are difficult to predict, the FTC's estimate is likely too low, and some companies may not track marketing expenditures and activities in the categories and the format the agency will request. The GMA/FPA stated that the cost of hiring financial and legal assistants to prepare a response could alone equal $25,000 for smaller companies and $50,000 for larger companies. The GMA/FPA suggested that the burden on companies is likely to correlate more closely to the number of brands a company markets, than the number of food categories in which it markets products.

The FTC cannot, however, determine in advance the number of brands for which each company will be required to provide data; this will depend on how the companies market their brands. Nor is it likely that each company will engage in an equal level of marketing for all brands. The FTC believes its ranges for estimated costs, which are separated into single-category and multiple-category company ranges, are sufficiently wide to account for differences in the number of individual brands the companies market in each category and in the amount of marketing the companies engage in for each brand.

4. Suggestions for Improvements to Proposed Information Collection

The FTC invited comments in its October 23 Notice on ways to enhance the quality, utility, and clarity of the information to be collected. Many of the comments the FTC received offered suggestions for enhancing the FTC's proposed collection of marketing data.

The PHI comments encouraged the collection of in-school marketing data, data on pricing strategies and consumer food purchases, and expenditures devoted to market research. PHI also recommended that the FTC seek information on the companies' product

[7] *See* Comment by Fred Cantor (Nov. 30, 2006).

[8] *See* Comment by Sheila Fleischhacker (Dec. 27, 2006).

portfolios and on any marketing resources devoted to developing, packaging, and promoting products that contribute to a healthy lifestyle. The Mercatus Center suggested that the FTC research and report on the new self-regulatory initiatives being undertaken by food and beverage industry members, including the revised CARU guidelines and the Children's Food and Beverage Advertising Initiative, as well as company-specific initiatives. Consumers Union urged the FTC to seek information on school-related marketing activities, request brand-specific information from companies, and collect marketing data broken down by race and ethnicity.

The CMPC members requested that the FTC include major child-oriented media companies in the information requests, in order to determine the percentage of advertising run in their media that is directed to children and promotes food and beverage products or companies, the reach of such advertising, and the revenue from such advertising. The CMPC members also urged the FTC to seek information on all major and emerging types of food marketing directed at children and teens, including in-school marketing activities, character licensing, celebrity endorsements, Internet, cell phone and other technological advertising, and viral and word-of-mouth marketing. The CMPC members further requested that the FTC require companies to provide information about any market research involving children, advertising exposure data, and demographic data for target audiences.

The GMA/FPA comments recommended that the FTC's information requests specify categories and terminology used in the ordinary course of business by manufacturers and advertisers, such as the Product Category Codes used by Nielsen Media Research. GMA/FPA also asked that the FTC not request data on in-store marketing activities, event marketing, character licensing, product packaging, or product placement, on the grounds that these types of marketing are not likely to be targeted to children and adolescents, and because expenditures and activities in these categories would be difficult to ascertain. GMA/FPA further requested that FTC limit the information requests to a discrete time period, such as a single fiscal year.

BKC recommended that the FTC send information requests regarding: the types of food and beverage products marketed to children (defined as ''consumers under the age of 13''); the amount of commercial time dedicated to advertising to children on television and radio; the types of print media, in-store marketing, events, packaging promotions, Internet activities, and product placements used to advertise to children; and the expenditures for television, radio, and print media advertisements directed to children. The PHLP urged the FTC to make its reporting requirements similar to those used in the FTC's tobacco industry information requests.

The CDHS encouraged the FTC to seek information on: All of the categories of data listed in the Senate Report;[9] trends for unmeasured media promotion, such as product placement, character licensing, special events, in-school activities, advergames, and promotions using music, cell phones, and sport and entertainment venues; price promotions and price points; and promotional and educational strategies directed toward particular population segments based on income-level, race/ethnicity, or age. CDHS also recommended that the FTC collect data by specific name brands, including the nutrition or caloric level of the food being advertised for comparison purposes, and that the FTC request the marketing portfolios for healthy foods as compared to all foods marketed by the companies. Finally, CDHS suggested that the FTC collect any qualitative research data studying children and youth, as well as scanner or other sales data for food and beverage products marketed to children, including cross-promotions.

One individual consumer asked that the Commission request data on celebrity endorsements, sweepstakes, product placements, and peer-to-peer advertising, as well as data showing the placement times for television advertisements directed to children.[10] Another consumer recommended that the FTC seek information on audience thresholds companies use to target particular age groups, and to request any market research the companies may have undertaken for particular advertising campaigns directed to children.[11] A third consumer suggested that the FTC seek information on: The demographic data industry uses to target marketing to particular ethnic or age groups; product profiles, to enable the FTC to analyze the amount expended on the marketing of items of greater or lower nutritional value; the expertise of any nutrition or health professionals who work or consult on marketing activities and the expenditures related to the hiring of such professionals; quantitative and qualitative assessments of marketing practices that emphasize physical activity in comparison to dietary choices; criteria for any nutritional icons used; and money spent on lobbying Congress on the issue of food marketing to children.[12]

Many of the proposals for improving the data collection are incorporated into the proposed Section 6(b) Orders, whose scope is discussed in detail in Part B.1. of this notice. For example, the FTC intends to request the companies to provide information regarding any new policies or initiatives they have undertaken to improve the nutritional profiles of the foods they market to children, and any other steps taken in response to the recommendations contained in the April 2006 Report on a Joint Workshop of the Federal Trade Commission and the Department of Health and Human Services.[13] In the main, however, the FTC believes that to produce a report that is comprehensive yet of manageable scope, the proposed Section 6(b) Orders should focus on the issues outlined in the Senate Report.

5. Suggestions for Minimizing the Burden of the Information Collection

In the October 23 Notice, the FTC invited comments on ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In response, the Mercatus Center stated that information on advertising in measured media is collected by various market research companies, and that it might be less costly to compel production of this information from such companies. However, the FTC seeks information on expenditures and activities in both measured and unmeasured media categories, and industry members are in the best position to provide responsive data. The data gathered by market research companies is too limited to provide an adequate substitute. The Mercatus Center commented that market research companies may be in a better position

[9] *See* note 2, *supra*.

[10] *See* Comment by Jill Pakulski (Oct. 30, 2006).

[11] *See* Comment by Fred Cantor (Nov. 30, 2006).

[12] *See* Comment by Sheila Fleischhacker (Dec. 27, 2006).

[13] *See* Federal Trade Commission & Department of Health and Human Services, *Perspectives on Marketing, Self-Regulation, & Childhood Obesity: A Report on a Joint Workshop of the Federal Trade Commission & the Department of Health and Human Services* 48–54 (Apr. 2006) (Joint Workshop Report), *available at http://www.ftc.gov/os/2006/05/PerspectivesOnMarketingSelf-Regulation&ChildhoodObesityFTCandHHSReportonJointWorkshop.pdf*.

to provide information on advertising time and exposure, but the proposed Section 6(b) Orders do not ask companies to provide this information.

The FTC's proposed Section 6(b) Orders seek information on expenditures and activities in both measured and unmeasured media categories, as further discussed in part B.1. of this notice. The GMA/FPA stated that the FTC should seek data only on measured media expenditures and activities in order to minimize the burden on industry members. Although GMA/FPA states that measured media activities account for the majority of marketing expenditures targeted to children and adolescents, other commenting parties made conflicting observations,[14] and the FTC staff's research found that industry members are currently engaged in a wide variety of unmeasured media activities to promote food and beverage products to children and adolescents. Moreover, Congress expressly requested that the report address expenditures and activities in both measured and unmeasured media categories, and a substantial number of the media categories for which information is sought in the proposed Section 6(b) Orders are taken directly from the Senate Report.

GMA/FPA further requested that, if information is sought on unmeasured media, the FTC should ask for best estimates of aggregated expenditures (rounded to the nearest multiple of $10 or $50 million), along with illustrations of the activities. The FTC will seek illustrations of unmeasured media activities in the proposed information requests. However, limiting reporting of expenditures to multiples of $10 or $50 million would not provide a sufficiently accurate or complete picture of the amount of unmeasured media activity in which the companies are engaged. Many Internet-based promotions, for example, are likely to cost the companies relatively little money and would not be captured if the reporting limit were set that high. The FTC proposes seeking data on expenditures rounded to the nearest $1,000.

The GMA/FPA also asked that the FTC provide a clear definition for marketing directed to children and adolescents. The proposed Section 6(b) Orders provide a detailed list of criteria for marketing expenditures and activities that companies must report. The FTC will examine reported data and determine which expenditures and activities are targeted to children and adolescents, and will report on these in the aggregate.

BKC commented that the information requests should be limited to marketing undertaken by companies at the centralized, corporate level, and should not include marketing that occurs at the regional, local, or individual franchise level. The FTC believes that limiting the requests in this fashion could result in the omission of valuable marketing data. If a company expends money on or approves activities in advertising or other promotional activities that are segmented by region, locality, or individual franchise, then the proposed Section 6(b) Orders would require the company to report these expenditures and activities; the company would not, however, be required to gather data not already in its possession on expenditures and activities independently undertaken by individual franchises.

The CDHS recommended that data be collected online and that, whenever possible, the FTC should use existing industry information consistent with conventional commercial measures. The CDHS stated that any costs to industry members in responding to the information requests were fair and reasonable given that the IOM recently reported that the food, beverage, and restaurant industries have approximately $900 billion in annual sales and spend more than $10 billion per year in marketing their products to children and youth. CDHS also pointed to the cost to the public and the U.S. health care system due to the consequences of physical inactivity, obesity, and overweight, which were approximately $28 billion in California alone in 2005. Again, the proposed Section 6(b) Orders will seek information consistent with commercially measured media, but will also seek information on non-commercially measured media expenditures and activities, as requested by Congress.

6. Other Requests Contained in Comments

The CDHS requested that information collected from the companies be made public and that data collection continue following the publishing of the FTC's report. The Mercatus Center also requested that the FTC create a publicly available database of any of the information collected that is not confidential or does not constitute trade secrets, so that other researchers could replicate the FTC's findings. The agency anticipates, however, that much of the information collected will be protected by law from public disclosure,[15] and anticipates reporting on marketing expenditures and activities in the aggregate.

One consumer asked the FTC to provide information on the selection process criteria for the targeted companies.[16] These criteria will be outlined in the FTC's final report. The PHLP requested that the FTC make reporting an ongoing requirement for food and beverage industry members. The FTC plans to complete the current report before considering proposals for future research. The agency is committed to ongoing monitoring of this subject area, however, and anticipates that it will continue to address issues raised by food marketing to children.

The Mercatus Center's comment suggested that the FTC evaluate a number of additional issues: the extent to which children and adolescents are exposed to and process advertisements targeted toward them; other factors that might cause a rise in obesity, such as physical inactivity and sedentary activities; and the possible beneficial aspects of advertising, such as educational effects. These issues, however, are beyond the scope of the report requested by Congress, and the FTC will not address them in the current report. The goal of the proposed information collection is to conduct a comprehensive review of food industry marketing activities and expenditures targeted to children and adolescents. The FTC expects that focusing its efforts in this manner will facilitate production of a high quality study that thoroughly responds to Congress's request.

B. Information Requests to Food and Beverage Industry Members

1. Description of the Collection of Information and Proposed Use

The FTC proposes to send information requests to forty-four (44) food and beverage manufacturers, distributors, and marketers and quick service restaurant companies in the United States. The companies that will receive these information requests are those marketing and selling the categories of food and beverage products that appear to be advertised to children and adolescents most frequently. The information requests will seek data and

[14] *See, e.g.*, Comments by Consumers Union (Dec. 18, 2006), at 2.

[15] Section 6(f) of the FTC Act, 15 U.S.C. 46(f), bars the Commission from publicly disclosing trade secrets or confidential commercial or financial information it receives from persons pursuant to, among other methods, special orders authorized by Section 6(b) of the FTC Act. Such information also would be exempt from disclosure under the Freedom of Information Act. 5 U.S.C. 552(b)(4).

[16] *See* Comment by Sheila Fleischhacker (Dec. 27, 2006).

information regarding, among other things: (a) The types of foods marketed to children and adolescents; (b) the types of measured [17] and unmeasured [18] media techniques used to market food products to children and adolescents; (c) the amount spent to communicate marketing messages about food products to children and adolescents in measured and unmeasured media; (d) the nature of the marketing activities in unmeasured media used to market food products to children and adolescents; and (e) any marketing policies, initiatives, or research in effect or undertaken by the companies relating to the marketing of food and beverage products to children and adolescents.

Note: subsequent to this notice, any destruction, removal, mutilation, alteration, or falsification of documentary evidence that may be responsive to this information collection within the possession or control of a person, partnership, or corporation subject to the FTC Act may be subject to criminal prosecution. 15 U.S.C. 50; *see also* 18 U.S.C. 1505.

Confidentiality: Section 6(f) of the FTC Act, 15 U.S.C. 46(f), bars the Commission from publicly disclosing trade secrets or confidential commercial or financial information it receives from persons pursuant to, among other methods, special orders authorized by Section 6(b) of the FTC Act. Such information also would be exempt from disclosure under the Freedom of Information Act. 5 U.S.C. 552(b)(4). Moreover, under Section 21(c) of the FTC Act, 15 U.S.C. 57b–2(c), a submitter who designates a submission as confidential is entitled to 10 days' advance notice of any anticipated public disclosure by the Commission, assuming that the Commission has determined that the information does not, in fact, constitute Section 6(f) material. Although materials covered under one or more of these various sections are protected by stringent confidentiality constraints, the FTC Act and the Commission's rules authorize disclosure in limited circumstances (*e.g.*, official requests by Congress, requests from other agencies for law enforcement purposes, and administrative or judicial proceedings). Even in those limited contexts, however, the Commission's rules may afford protections to the submitter, such as advance notice to seek a protective order in litigation. *See* 15 U.S.C. 57b–2; 16 CFR 4.9–4.11.

Finally, the information presented in the report will not reveal company-specific data, except data that are public. *See* 15 U.S.C. 57b–2(d)(1)(B). Rather, the Commission anticipates providing information on an anonymous or aggregated basis, in a manner sufficient to protect individual companies' confidential information, to provide a factual summary of food industry marketing activities and expenditures targeted to children and adolescents.

a. Information About Food Products Marketed to Children and Adolescents

The proposed Section 6(b) Orders will seek information about the categories of food products, the specific brands, and the sub-brands or brand variants that the companies market to children and adolescents. The Orders will specify eleven (11) food categories for which companies will have to report marketing expenditures and activities, and will list the corresponding Product Category Codes from Nielsen Media Research. In some cases, the FTC's food categories will be more limited than Nielsen's Product Category Codes, and the agency will make this clear in the Orders.

The specific categories for which the FTC will request data are: Breakfast cereals; snack foods; candy; dairy products, including milk and yogurt; baked goods; carbonated beverages; fruit juice and non-carbonated beverages; prepared foods and meals; frozen and chilled desserts; and quick service restaurant items. FTC staff has identified these as the categories of food and beverage products that appear to be advertised to children and adolescents most frequently. In addition, the FTC proposes to collect information from major marketers of fruits and vegetables to ensure that data are gathered regarding efforts to promote consumption of these foods among children and adolescents.

The proposed Section 6(b) Orders will also request information on whether the companies offer a line of food products bearing a nutritional icon, seal, or symbol, or otherwise identified as ''better for you,'' healthier, more nutritious, lower calorie, or lower fat than other products, and will seek information on how those product lines are marketed to children and adolescents. This information will help the agency evaluate the variety of foods and beverages that is marketed to children and adolescents.

b. Information About Measured and Unmeasured Media Techniques Used To Market Food Products to Children and Adolescents

The proposed Section 6(b) Orders will require the companies to provide their marketing activities and expenditures during the calendar year 2006 in a number of measured and unmeasured media categories. Specifically, the Orders require that data on expenditures and activities be broken down into 20 media categories.[19]

Thus, the proposed Section 6(b) Orders seek comprehensive information about activities and expenditures to promote food and beverages to children and adolescents, including most of the information suggested in the comments. This information will allow the agency to analyze how industry members allocate their promotional activities and expenditures among various measured and unmeasured media types for different food products. The categories are carefully defined to facilitate compliance with the requests, as are the criteria for determining whether particular marketing activities and expenditures must be included in the responses.

c. Information About Expenditures in Measured and Unmeasured Media To Market Food Products to Children and Adolescents

The proposed Section 6(b) Orders will require industry members to report expenditures in each of the measured and unmeasured media categories by food category, by brand,[20] and, where such advertising exists, by sub-brand or brand variant, and to identify expenditures for products that are part of a nutritional product line. Expenditures will be reported separately for marketing activities directed to children ages 2–11 and for those directed to adolescents ages 12–17. This information will allow the agency to analyze how industry members allocate their promotional expenditures among

[17] ''Measured media'' includes methods such as television, radio, print (magazine and newspaper), and some forms of Internet advertising.

[18] ''Unmeasured media'' includes methods such as in-store marketing (including shelf placement), events, package promotions, and product placement in entertainment media (including television shows, movies, video games, and music recordings).

[19] These are: Television advertising; radio advertising; print advertising; movie theater/video/video game advertising; company-sponsored Internet sites; other Internet advertising; other digital advertising; in-store advertising and promotions; specialty item or premium distribution; public entertainment events; product placements; character licensing and cross-promotions; sponsorship of sports teams or individual athletes; packaging and labeling; word-of-mouth marketing; viral marketing; celebrity endorsements; in-school marketing; advertising in conjunction with philanthropic endeavors; and other expenditures.

[20] For any advertising or other promotional activity for non-branded fruit, vegetable, or dairy products, expenditures will be reported by the individual fruit, vegetable, or dairy product varieties; for restaurant items, expenditures will be reported by restaurant chain.

particular food and beverage products and particular media for each age group.

Total marketing expenditures for each food category, brand, and sub-brand or brand variant will also be reported to permit the agency to analyze the percentage of marketing expenditures for any product or in any media category that is directed to children or adolescents. Similarly, the proposed Orders will ask the companies to identify any marketing expenditures that are directed to individuals of a specific race, ethnicity, or gender.

d. Information About Marketing Activities in Unmeasured Media Used To Market Food Products to Children and Adolescents

The proposed Section 6(b) Orders will require the companies to provide samples of (or to describe, if providing samples is not practicable) the specific advertising and promotional activities undertaken in each of the unmeasured media categories (including all Internet advertising) for which qualifying expenditures are reported or for which there are qualifying activities for which no expenditures are reported.

In addition to requesting that the FTC report on marketing expenditures, Congress expressly instructed the FTC to address food industry marketing activities that are targeted to children and adolescents. Whereas marketing activities in television, radio, and print media are relatively uniform, research by FTC staff indicates that industry members employ a wide variety of marketing techniques in unmeasured media to promote food and beverage products to children and adolescents. In addition, some activities, such as product placements and viral and word-of-mouth marketing activities, may occur as cross-promotions or in another context in which no actual costs are incurred. By collecting samples and descriptions of these activities from industry members, the agency will be able to provide Congress and the public with a complete picture of the types of marketing techniques the industry is using to reach children and adolescents.

e. Information About Marketing Policies, Initiatives, and Research

The proposed Section 6(b) Orders will seek information about any company policies pertaining to the marketing of food and beverage products to children and adolescents, including any policies or programs undertaken or implemented by the companies to encourage healthy eating and lifestyle choices by children and adolescents. The Orders will also request copies of any market research sponsored or undertaken by the companies to measure the appeal of certain food products or marketing activities to children and adolescents.

Responses will enable the companies to show any changes in their future marketing plans and policies that might not be reflected in their reports of past marketing expenditures and activities. The information will also allow the agency's report to address any anticipated changes in the marketing of food and beverage products to children and adolescents, and will permit the agency to evaluate any adoption by the companies of the recommendations contained in the April 2006 Joint Workshop Report.[21] Information on market research sponsored or undertaken by the companies will enable the agency to evaluate the companies' process for selecting food products or marketing techniques to reach children and adolescents.

2. Estimated Hours Burden: 6,000 hours (rounded to the nearest thousand). The FTC staff's estimate of the hours burden is based on the time required to respond to each information request. The Commission intends to issue the information requests to 44 parent companies of food and beverage and quick service restaurant advertisers. Because these companies vary in size, in the number of products they market to children and adolescents, and in the extent and variety of their marketing and advertising, the FTC staff has provided a range of the estimated hours burden.

Based upon its knowledge of the industries, the staff estimates, on average, that the time required to gather, organize, format, and produce such responses will range between 80–120 hours per information request for companies that market a single category of product to children and adolescents. The FTC staff estimates that companies that market multiple categories of products to children and adolescents would spend between 120–300 hours to respond to an information request. The total estimated burden per company is based on the following assumptions:

Identify, obtain, and organize product information, prepare response: 15–35 hours

Identify, obtain, and organize information on marketing expenditures, prepare response: 15–75 hours

Identify, obtain, and organize information on and samples of marketing activities, prepare response: 40–160 hours

Identify, obtain, and organize information regarding marketing policies and research, prepare response: 10–30 hours

Total: 80–300 hours

The Commission intends to send 27 information requests to parent companies that market a single category of product to children and adolescents. As a result, staff estimates a total burden for these companies of approximately 2700 hours (27 companies × 100 average burden hours per company). The Commission intends to send 17 information requests to parent companies that market multiple categories of products to children and adolescents. As a result, staff estimates a total burden for these companies of approximately 3570 hours (17 companies × 210 average burden hours per company). Thus, the staff's estimate of the total burden is approximately 6270 hours. These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent company that has received the information request.

3. Estimated Cost Burden: $1,568,000 (rounded to the nearest thousand)

It is difficult to calculate with precision the labor costs associated with this data production, as they entail varying compensation levels of management and/or support staff among companies of different sizes. Financial, legal, marketing, and clerical personnel may be involved in the information collection process. The FTC staff has assumed that professional personnel and outside legal counsel will handle most of the tasks involved in gathering and producing responsive information, and has applied an average hourly wage of $250/hour for their labor. Thus, the staff estimates that the total labor costs for the information requests will be approximately $1,567,500 (($250 × 2700 hours for companies that market a single category) + ($250 × 3570 hours for companies that market multiple categories)).

FTC staff estimates that the capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may necessitate that industry members maintain the requested information provided to the Commission, they should already have in place the means to compile and maintain business records.

William Blumenthal,

General Counsel.

[FR Doc. E7–7375 Filed 4–17–07; 8:45 am]

BILLING CODE 6750–01–P

[21] *See* note 13, *supra*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advancing System Improvements to Support Targets for Healthy People 2010 (ASIST2010)

AGENCY: Office on Women's Health, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Announcement Type: Competitive Cooperative Agreement FY 2007 Initial Announcement.

Funding Opportunity Number: Not applicable.

Catalog of Federal Domestic Assistance: The Catalog of Federal Domestic Assistance number is 93.088.

DATES: Proposals are due no later than 5 p.m. Eastern Time on June 18, 2007. The application due date requirement in this announcement supersedes the instructions in Form OPHS–1.

ADDRESSES: To receive consideration, applications must be received by the Office of Grants Management (OGM), Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS) c/o WilDon Solutions, Office of Grants Management Operations Center, 1515 Wilson Boulevard, Third Floor, Suite 310, Arlington, VA 22209, Attention Office on Women's Health, ASIST2010.

Authority: This program is authorized by 42 U.S.C. 300u–2(a).

Purpose and Eligibility: The purpose of this Request for Applications (RFA) is to use a public health systems approach to improve performance on two or more Healthy People 2010 (HP 2010) objectives that target women and/or men in the Focus Areas specified in this RFA. There must already be an existing source for baseline data for the objectives selected by the applicant and the applicant must already be a participant in an existing public health system/collaborative partnership. Eligible applicants are public and private organizations (public and private academic institutions and hospitals); community-based and faith-based organizations; medical groups/practices, and organizations with women's and men's health experience with funding lasting through September 30, 2010, that will help support the proposed program activities. State, county, and local health departments and tribes and tribal organizations are also eligible to apply.

SUMMARY: The DHHS Office on Women's Health (OWH) was established in 1991 to improve the health and well being of all women and girls in the United States (US). To achieve this long-term goal, the OWH focuses on reducing the health differences (disparities) between women and men, between girls and boys, and among populations of women by supporting programs such as the 48 Multidisciplinary Health Models for Women sites throughout the U.S. Each site has implemented its own paradigm and blend of services to fit the needs of its community. The National Centers of Excellence in Women's Health (CoEs), National Community Centers of Excellence in Women's Health (CCOEs), and the CoE- and CCOE-Ambassadors for Change (AFCs), in particular, have served as leaders and change agents in the area of women's health. Their pioneering efforts have led to changes in the way women's health services are delivered, changes in women's health curricula, acceptance of community health workers and allied health professionals as key members of the care delivery team, development of leadership and empowerment programs for women, and much more. These programs have also demonstrated that, on a local level, the formation of collaborative partnerships across schools, clinics, and disciplines within the academic community, and among community-based organizations with similar missions, leads to broader outreach, the delivery of more counseling and preventive services, improved access to more comprehensive services, and greater patient satisfaction. More information about these programs can be found at *http://www.womenshealth.gov/owh/multidisciplinary/*.

A recent literature review commissioned by the OWH (Literature Review on Effective Sex- and Gender-Based Systems/Models of Care, 2007, also available at (*http://www.womenshealth.gov/owh/multidisciplinary/reports/GenderBasedMedicine/*) to help guide the development of this RFA, reports that the comprehensive, integrated, multidisciplinary models of women's health care, first implemented by OWH about a decade ago, have helped to raise awareness of women's health issues and have helped to establish women's health as a discipline. A recommendation made was that it is time for OWH to move to a broader sex- and gender-based approach to health care, building on the success of its comprehensive, integrated, multidisciplinary models programs. The literature review addressed several broad questions and contains interesting and useful information on a variety of topics relevant to this RFA. The information on sex and gender [1] differences in the current healthcare system, the effectiveness of sex- and gender-based healthcare practices, the effectiveness of a sex- and gender-based focus on clinical care, and the effectiveness of patient advocates/navigators in getting men into the healthcare system and to needed care may be useful background information for applicants.

Healthy People 2010

Healthy People 2010 is a comprehensive, national disease prevention and health promotion agenda designed to improve the health of all people in the U.S. during the first decade of the 21st century. Healthy People 2010 build on initiatives implemented over the past 20 years including:

1. Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention (1979),
2. Promoting Health/Preventing Disease: Objectives for the Nation (1980), and
3. Healthy People 2000: National Health Promotion and Disease Prevention Objectives (1960).

The two overarching goals of Healthy People 2010 are to increase years and quality of healthy life and to eliminate health disparities. These two goals are supported by specific objectives in 28 Focus Areas. Healthy People 2010 documents are available online at the Healthy People Web site: *http://www.healthypeople.gov/*. A midcourse review of HP 2010 objectives was completed recently. The current list of Healthy People 2010 objectives assessed at the midcourse review and the results are available at: *http://www.healthypeople.gov/Data/midcourse.*

The OWH believes in the value of a public health systems approach to improve health outcomes. Therefore, the OWH is planning to provide three years of funding to support public health systems and/or collaborative partnerships with baseline data available that put a gender focus on the following HP 2010 Focus Areas:

- 3—Cancer,
- 5—Diabetes, and/or

[1] The definition of sex and gender used in this RFA is based on the Institute of Medicine report titled *Exploring the Biological Contributions to Human Health. Does Sex Matter?* It defines sex as a classification generally of male and female according to reproductive organs and function that derive from the chromosomal complement. The term gender is defined as a person's self representation as a male or female and how that person is responded to by social institutions on the basis of individual gender presentations.

• 12—Heart Disease and Stroke, leading causes of death among women and men, and their objectives, crosscut with Focus Areas:

• 1—Access to Quality Health Services,

• 7—Educational and Community-Based Programs,

• 19—Nutrition and Overweight, and

• 20—Physical Activity and Fitness, and their objectives.

For example, an applicant may have as their program goal the reduction of the proportion of adults with high blood pressure (Focus Area 12/Objective 9) and an increase in the proportion of adults with high blood pressure whose blood pressure is under control (Focus Area 12/Objective 10) by increasing the proportion of adults with a usual primary care provider (Focus Area 1/Objective 5). The applicant may choose to focus on a subpopulation of the adult population. The OWH believes that a gender-focused approach will help improve the health of U.S. women and girls as well as men and boys; improve the quality of care provided; reduce disparities among women, among men, and between women and men; and potentially, reduce overall health care costs by reducing duplication of services.

Therefore, the OWH is implementing a new program titled: Advancing System Improvements to Support Targets for Healthy People 2010 (ASIST2010). The goals of ASIST2010 are: (1) To provide additional support to existing public health systems/collaborative partnerships to enable them to add a gender focus to HP 2010 objectives that track the health status of women and/or men, to help improve gender outcomes in the targeted population and/or geographic area, (2) improve surveillance/information systems that allow tracking of program progress on HP 2010 objectives at the grantee level, and (3) develop and implement a plan to sustain the program after OWH funding ends.

Purpose

The purpose of this new initiative is to use a public health systems approach to improve performance on two or more HP 2010 objectives that target women and/or men in the Focus Areas specified above. To enhance an applicant's chance of meeting its goal(s) and objective(s), in addition to the OWH program goals, within the grant's three-year project period, applicants are encouraged to use evidence-based strategies to implement their program. A brief summary of the evidence-based strategy(ies) and references must be included in the program narrative.

There are over 300 measurable HP 2010 objectives in the 28 HP 2010 Focus Areas tracking data specific for women and men. To be responsive to the RFA, applicants must select at least one of the objectives in the OWH specified disease Focus Areas 3-Cancer, 5-Diabetes, and/or 12-Heart Disease and Stroke, and at least one of the objectives in the four cross-cutting areas specified by OWH-1-Access to Quality Health Services and 7-Educational Community-Based Programs, 19-Nutrition and Overweight, and/or Physical Activity and Fitness. Applicants may focus on data collection among groups of women, among groups of men, or between groups of women and men. For example, an applicant may decide to select the following HP 2010 objectives:

• Reduce the proportion of adults with high blood pressure (Objective 12–9 under Focus Area 12),

• increase the proportion of persons with high blood pressure with their blood pressure under control (Objective 12–10 under Focus Area 12), and

• increase the proportion of persons with a usual primary care provider (Objective 1–5 under Focus Area 1), provided that regional, State, tribal, and/or county baseline data are available for these objectives.

Applicants should describe activities in their targeted area that are addressing the objectives selected and how their approach will help move the objectives toward its national, State, or county target. The applicant must also describe the evidence-based strategy(ies) that will be used to achieve the desired outcome—a reduction in the proportion of adults with high blood pressure, an increase in the proportion of people with high blood pressure with their blood pressure under control, and an increase in the proportion of persons with a usual primary care provider in State X. The applicant must identify specific short-term outcomes that will support the achievement of the HP 2010 objectives selected and describe how the outcomes will be achieved and measured. Additionally, all applicants must:

(1) Establish a surveillance/information system to track information on clients served to measure progress toward targets,

(2) Implement a gender-based program focus, and

(3) Develop and implement a plan to sustain the program after OWH funding ends. Applicants proposing to perform only these three activities will not be considered responsive to the RFA.

The applicant must also report which HP 2010 objectives will be targeted in Table 1, baseline data in Table 2, target population data in Table 3, and implementation strategies in Table 4. All tables referenced in this RFA are included in the Application Kit which may be obtained by accessing *http://www.grants.gov* or the eGrants system at *http://www.GrantSolutions.gov.* A hard copy of the Application Kit may be obtained by contacting WilDon Solutions at 1–888–203–6161. See Section IV for more instructions on how to obtain an Application Kit. The information provided in the tables must support the narrative.

Public Health Systems Definition

For the purpose of this RFA, a public health system is defined as an established, collaborative partnership between governmental and non-governmental partners such as public and private academic institutions and hospitals, medical groups/practices, community-based and faith-based organizations, tribes and tribal organizations, organizations with expertise relevant to the HP 2010 objectives selected by the applicant, State Women's Health Coordinators (SWHCs), and organizations with women's and men's health and gender-focused programs and experience. A list of SWHCs is available at: *http://www.womenshealth.gov/owh/about/swhc.cfm.* Through collaboration on identified HP 2010 Focus Areas and objectives, the public health system works to create positive change that leads to improved outcomes for women and girls and/or men and boys. The public health system may be enhanced with additional partners in order to be responsive to the requirements of this RFA. Using the funds provided by OWH to add a gender focus to two or more of the seven Focus Areas listed below, the system will implement evidence-based strategies to achieve the Focus Area objectives identified by the applicant. The public health system must also address gender health issues across the lifespan using a comprehensive, integrated, multidisciplinary approach and be sustainable after OWH funding ends. At least a third of the partners within the public health system should have experience with gender focused programs.

The primary goal of the public health systems-level change envisioned by OWH is improvements in performance on one or more of the HP 2010 objectives selected by the applicant, specifically related to the seven HP 2010 Focus Areas identified by OWH:

• 1—Access to Quality Health Services,

• 3—Cancer,

• 5—Diabetes,

- 7—Educational and Community-Based Programs,
- 12—Heart Disease and Stroke,
- 19—Nutrition and Overweight, and
- 20—Physical Activity and Fitness.

Systems change has been used to extend cultural competence; to deliver more comprehensive, integrated, multidisciplinary care; to accommodate women in various environments; and to improve performance management in health care, to cite a few examples.

SMART Outcomes

Program outcomes must be specific, measurable, achievable, relevant, and timely (SMART). SMART objectives are clear and leave no room for interpretation. At a minimum, outcomes must be inclusive of sex, gender, age and race/ethnicity. If available, information on education level, insurance coverage, income level, disability status, and other socio-demographic variables should also be reported. The outcomes should be consistent with the tribal, county, State, or regional HP 2010 baseline and/or target data available. Although tribal, county, State, or regional targets may not match the National targets, they should be consistent with the HP 2010 plan in the State or area where the grant program will be implemented. If a State plan and/or State HP 2010 Midcourse Review is not available, applicants may use another source to provide the baseline data and to justify the need to focus the objectives selected for its community. Applicants are encouraged to contact their State Health Department to obtain a copy of their State HP 2010 Midcourse Review. Some targets may have been revised as a result of the review.

I. Funding Opportunity Description

Many programs operate with little or no attention to women and gender issues and, thus, may have a limited positive impact on achieving the HP 2010 targets or on catalyzing progress toward the HP 2010 targets. The purpose of the ASIST2010 program is for the OWH to provide three years of funding to existing public health systems/collaborative partnerships to add a gender focus to two or more of the Focus Areas and objectives targeted by this RFA. To enhance an applicant's chance of meeting its objectives within the grant's three-year project period, applicants must use evidence-based strategies to implement their program.

Public and private organizations with current funding through August 31, 2010, that supports proposed ASIST2010 activities; tribes; and, county, State, and local health departments are encouraged to expand existing partnerships, if necessary, to address at least two of the seven HP 2010 Focus Areas targeted by this RFA. As these public health systems/collaborative partnerships work to achieve ASIST2010's purpose, they should strive to create a system change similar to the efforts of the:

(1) Evidence Based Disease and Disability Prevention Programs funded by the Administration on Aging (*http://www.aoa.gov/prof/evidence/aoa_ahrq_2006_overview.pdf*);

(2) Racial and Ethnic Approaches to Community Health (REACH) 2010 funded by the Centers for Disease Control and Prevention (*http://www.cdc.gov/reach2010*);

(3) the Health Resources and Services Administration Disparities Collaboratives (*http://www.healthdisparities.net/hdc/html/library.aspx?documentID=9–12–2006.2610&folderopen=yes*);

(4) Mental Health System Transformation Grants funded by the Substance Abuse and Mental Health Services Administration (*http://www.samhsa.gov/pubs/mhc/MHC_Transformation.htm*);

(5) Accelerating Change and Transformation in Organizations and Networks funded by the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/research/action.htm*);

(6) Clinical and Translational Science Awards funded by the National Institutes of Health (*http://www.ncrr.nih.gov/clinicaldiscipline.CTSA_FactSheet.pdf*); and

At a minimum each ASIST2010 applicant must:

(1) Have in place, at the time the application is submitted, a public health system/collaborative partnership that includes a mix of the following types of organizations—public and private academic institutions and hospitals, medical groups/practices, community-based and faith-based organizations, tribes and tribal organizations, organizations with expertise relevant to the HP 2010 objectives selected, State Women's Health Coordinators (SWHCs), and organizations with demonstrated experience addressing gender issues through appropriate interventions/programs;

(2) describe how the current public health system/collaborative partnership operates (provides comprehensive, integrated, interdisciplinary care; primary care; education and outreach; community health planning; etc.), whether it has addressed one or more HP 2010 objectives, and whether any health or social issues addressed by the system have a gender focus;

(3) List the funding sources already available to the applicant and the partners that will last at least through August 31, 2010, that could be used to help support the proposed ASIST2010 program activities;

(4) Describe how the public health system/collaborative partnership and target area will be enhanced with the addition of a gender focus;

(5) State clearly the HP 2010 focus areas and objectives that will shape the grant activity and why these objectives are important to the tribe, county, region, or State;

(6) Have demonstrated experience in the objectives selected and in women's and men's health and gender-focused programs;

(7) Describe in detail how objectives will be achieved over the funding period and how progress toward the selected objectives will be tracked and measured annually;

(8) Demonstrate that the objectives of the grant are SMART (assistance writing SMART objectives are available at *http://www.cdc.gov/nchstp/tb/Program_Evaluation/Guide/AppB_Writing_Smart_Objectives.htm;*

(9) Provide the baseline and target data for the selected objectives—tribal-, county-, State-, or regional-level data related to the objectives are required with a discussion of how the tribal, local, county, or State targets cascade from the HP 2010 targets;

(10) State target(s) and short- and long-term outcome measure(s) for the next 3 years and the applicant's plan/strategy for reaching the targets;

(11) State the total population to be reached by the initiative and describe activities to reach the population;

(12) Establish a Steering Committee that includes, at a minimum, a representative from each partner organization and a lay community person to help oversee and monitor the implementation of the proposed program—Also use Table 6 in the Application Kit to provide a complete list of Steering Committee members;

(13) Provide a comprehensive description of how the program will be evaluated;

(14) Provide a partnership plan that describes in detail the role of each partner, the service(s) to be provided, the individual responsible for coordinating the services at the partner organization, how resources will be distributed among the partners (Table 5), and a signed Memorandum of Agreement (MOA) for each partner (A sample MOA is provided in the Application Kit.);

(15) Demonstrate relevant involvement of partners in the development of the application and plans to carry out the proposed activities—Applicants must also complete Tables 5, 6, and 7 included in the Application Kit and provide all information requested; and

(16) Provide a clear plan to continue the proposed activity(ies) after OWH funding has ended.

II. Award Information

The ASIST2010 program will be supported through the cooperative agreement mechanism. The OWH anticipates making these 3-year awards in FY 2007. The anticipated start date is September 1, 2007, and the anticipated period of performance is September 1, 2007, through August 31, 2010. Approximately $4,000,000 is available to make awards between $150,000-$500,000 total cost (direct and indirect costs) each year for the three-year project period. The number of awards made is contingent upon the quality and type of applications received, the amount of funds requested, and the availability of Federal funds. The total amount requested by an applicant must be based on the scope of the proposed program activity(ies) and justified clearly. At a minimum, all applicants will address at least two HP 2010 Focus Areas and at least one objective within each Focus Area and target a specific geographic area (region, State, or county) and/or a specific population. Normally, applicants proposing to perform the minimum activities allowed by the RFA, as described above, would request funding at the lower end of the $150,000–$500,000 funding range. However, for this announcement, if an applicant proposes to serve a county with a population of over one million people or a county with a metropolitan area with over one million people, serve a rural area where outreach may be more costly, or have a unique situation, they may need to request funding at the upper end of the funding range. Therefore, it is crucial that applicants provide detailed justification for every aspect of their budget requests.

The OWH will provide the technical assistance and oversight necessary for the implementation, conduct, and assessment of ASIST2010 program activities.

The applicant shall:

1. Implement the program described in the application according to the timeline that should be included in the Management Plan.

2. Participate in and pay for attendance at two annual meetings of ASIST2010 grantees in the Washington, DC Metropolitan Area. The cost of these meetings (including travel, lodging and meals) should be included in the applicant's budget.

3. Participate in a full-day orientation meeting in the Washington, DC Metropolitan Area within two months after the award of the grant. In Year 1 of the grant, this orientation meeting will count as one of the two meetings budgeted in the grant application. It is up to the applicant to decide and budget for the number of people that will participate in the orientation meeting.

4. Participate in additional ASIST2010 working groups, special interest meetings, or other opportunities. The OWH will pay for the travel and lodging for these meetings.

5. Adhere to all program requirements specified in the RFA and the Notice of Grant Award.

6. Submit required quarterly reports and an annual progress and Financial Status reports by the due dates stated in this announcement and the Notice of Grant Award, following the format for the quarterly report that will be distributed at the orientation meeting.

7. Ensure that appropriate staff is available to meet with the site visit team and provide a comprehensive report on the status of all grant activities.

8. Identify clearly the HP 2010 objectives to be addressed by the proposed program.

9. Describe in detail the evidence-based program(s) to be implemented to achieve the program objectives.

The Federal Government will:

1. Conduct a pre-award site visit to applicants that score in the funding range.

2. Organize and participate in all grantee meetings held in the Washington Metropolitan Area.

3. Review and decide upon requested project modifications.

4. Site visit ASIST2010 grantees at least once a year to provide advice and guidance on implementing the program and to help monitor progress toward goals.

5. Review all reports submitted by the grantees.

6. Monitor all grant activity and provide advice and guidance on the implementation of the grant program.

III. Eligibility Information

1. *Eligible Applicants.* Eligible applicants are public and private organizations (public and private academic institutions and hospitals); community-based and faith-based organizations; and medical groups/practices with existing funding lasting through September 30, 2010, that will help support the proposed ASIST2010 activities, and State, county, or local health departments and tribes and tribal organizations with expertise and experience in the proposed objectives.

Applicant organizations must already participate in an existing public health system/collaborative partnership. List the funding available for the applicant and the partners using Tables 7 and 8 in the Application Kit. Although one organization should be the lead applicant, the applicant must demonstrate involvement of the partners in the development of the application and in the planning and execution of the grant activities. At least one third of the partners should have demonstrated experience addressing gender differences through appropriate interventions, programs, or research related to the selected objectives. Single-site efforts are not eligible for this award.

2. *Cost Sharing or Matching Funds.* Cost sharing or matching funds are not required for this program.

IV. Application and Submission Information

1. *Address to Request an Application Kit:* Application Kits may be obtained by accessing Grants.gov at *http://www.grants.gov* or the GrantSolutions system at *http://www.GrantSolutions.gov.* To obtain a hard copy of the Application Kit, contact WilDon Solutions at 1–888–203–6161. Applicants may fax a written request to WilDon Solutions at (240) 453–8823 or email the request to *OPHSgrantinfo@teamwildon.com.* Applications must be prepared using Form OPHS–1, which can be obtained at the websites noted above.

2. *Content and Form of Application and Submission:* At a minimum, each application for a cooperative agreement grant funded under this announcement must include the information listed below to be considered for funding:

(a) A collaborative partnership that includes a mix of the following types of organizations—public and private academic institutions and hospitals, medical groups/practices, community-based and faith-based organizations, tribes and tribal organizations, and organizations with expertise relevant to the HP 2010 objectives selected, SWHCs, and organizations with women's health and gender-focused programs and experience;

(b) A description of the present system, its accomplishments to date as related to HP 2010 objectives or gender-based activities, and a description of how a gender focus and increased funding will enhance the effectiveness

and efficiency of the public health system/collaborative partnership;

(c) The type, source, purpose, and duration of funding the applicant and the partners have to help support the activities proposed for this initiative as well as the contact information for the Principal Investigator/Program Director;

(d) A clear statement of HP 2010 Focus Areas and objectives that will be addressed by the grant and how they will benefit the community, county, region, State or tribe;

(e) A description demonstrating experience with the objectives selected and in women and men's health/gender health and gender-focused programs;

(f) A comprehensive implementation plan that describes how objectives and outcomes will be achieved over the funding period and how progress towards objectives' targets and program outcomes will be tracked and measured annually;

(g) Baseline and target data for the objectives and the population that will be the focus of the selected objectives, the targets for the next three years, and the plan/strategy of reaching the targets;

(h) A description of the total population to be reached by the proposed grant program and a description of activities to reach the population;

(i) A clear statement of the applicant's targets and short- and long-term outcome measures for the three years and the applicant's plan/strategy for reaching the targets;

(j) A Steering Committee to oversee and monitor the implementation of the work plan that includes, at a minimum, a representative from each partner organization and a lay community person;

(k) A comprehensive description of the program evaluation plan;

(l) A partnership plan that describes in detail the role of each partner, the service(s) to be provided, the individual responsible for coordinating the services at the partner organization, how resources will be distributed among the partners, and a signed Memorandum of Agreement (MOA) for each partner;

(m) A discussion demonstrating relevant involvement of the partners in the development of the application and plans to carry out the proposed program activities; and

(n) A clear plan to continue the proposed activity(ies) after OWH funding has ended.

The Project Narrative must not exceed a total of 30 double-spaced pages, excluding the appendices. All pages must be numbered clearly and sequentially. The application must be typed double-spaced on one side of plain 8″ x 11″ white paper, using at least a 12 point font, and 1″ margins all around. The application should be organized in accordance with the format presented below. The information to be included in the ''Project Narrative'' section is also presented below.

Applications submitted via hard copy must be stapled and/or otherwise securely bound. Applicants are required to submit an original ink-signed and dated application and two photocopies. Applications not adhering to this guidance may not be reviewed. All applicants must pay particular attention to structuring the narrative to respond clearly and fully to each Review Factor and associated review criteria.

Background

A. Describe the current public health system/collaborative partnership and why the public health system/collaborative partnership was formed.

B. Describe the population and geographic area served by the current public health system/collaborative partnership and the services provided.

C. Provide an overview of the applicant's organization and experience related to the selected HP 2010 Focus Areas and objectives and with other HP 2010-related programs and/or activities.

D. Describe experience/involvement with women's and/or men's health and gender-focused programs.

E. Describe experience implementing and managing comprehensive, integrated, multidisciplinary programs.

F. Describe the public health system/collaborative partnership's experience with the HP 2010 initiative.

G. State goal and purpose of the proposed program. Include the number and demographics of the population to be served by the program. Use Table 6 to provide the demographic information on the targeted population.

H. Describe changes to the public health system/collaborative partnership to fulfill the proposed program's purpose.

I. Describe how the public health system/collaborative partnership will be enhanced with a gender focus.

Implementation Plan

A. State the disease Focus Area and objective(s) and the cross-cutting Focus Area and objective(s) to be addressed by the system using Table 1 in the Application Kit.

B. Provide baseline data for HP 2010 objectives and targets for the program in Table 2.

C. Describe the evidence-based strategy(ies) to be implemented to reach the objectives within the 3-year funding period and plans for implementing it. Also use Table 4 to present this information.

D. Describe the program outcomes and tasks to be accomplished during the 3-year funding period. List the tasks, the individual or organization with the lead responsibility for completion of the task, and the period of time required to complete the tasks (Table 5).

E. Describe programs and activities already in place to help support the selected Healthy People 2010 objectives. Include partners' programs and activities (Table 7).

F. Describe the role each partner will play in the implementation of the proposed program tasks to ensure that the tasks are accomplished by the dates reported in the timeline.

G. Describe the resources already available and/or the resources that will be made available to support each task. Use Tables 7 and 8 to report this information in detail.

H. Describe the composition of the Steering Committee, their role, and how their advice and guidance will be conveyed, implemented, and monitored. Use Table 6 to provide more detailed information about each member of the Steering Committee.

Partnership Plan

A. Provide a complete list of partners using Table 5, their primary area(s) of expertise, and their role/responsibility to ensure that the proposed program's goals and the HP 2010 selected objectives' targets are met (Table 5).

B. Describe partners' role in the development of the application.

C. Include in the appendix of the application signed MOAs that specify the services the partners will provide and the contact information for the person serving as the main liaison for the partnering organizations. A sample MOA is provided in the Application Kit. Letters of support are not required for this proposal.

D. Describe how resources will be distributed among the partners.

E. Describe how partner activities will be factored into measurements of progress toward achieving selected HP 2010 targets.

F. Describe the role of the State Women's Health Coordinator.

Management Plan

A. List key program staff and provide resumes for all budgeted and in-kind staff.

B. Describe staff experience and how it relates to their project responsibilities.

C. Describe the relationship of the Steering Committee, partners, and the applicant organization.

D. Provide an organizational chart depicting the grant administration structure.

E. Provide a task chart/timeline with projected start and end dates for all program activities. This timeline should depict all program activities including reports, meetings, etc. and is in addition to the timeline for program tasks presented in Table 4.

F. Discuss how the program's progress will be monitored and strategies for keeping tasks on track.

G. Describe how partner activities will be monitored and assessed.

Evaluation Plan

A. Describe the program evaluation methodology.

B. Describe the surveillance system implemented for the program.

C. List the program objectives using SMART style and how these objectives will be met.

D. Describe the data sources and how the data will be obtained.

E. Describe how progress towards objectives and targets will be tracked and measured.

F. Describe short- and long-term program outcomes and how they will be tracked and measured.

G. Include a timeline for the evaluation.

Sustainability Plan

A. Provide a clear, detailed plan to sustain the public health system/collaborative partnership and program activities after OWH funding ends.

B. Describe the goal and purpose of sustaining the program beyond 2010.

C. Describe the benefits of sustaining the program (e.g., maintenance of the health benefits achieved through the initial program).

D. Describe how the program will be sustained/institutionalized.

E. Describe experience sustaining past programs.

F. Describe any factors in the program design and implementation plan or with the applicant and partners' organizational settings that may facilitate sustainability.

Appendices

A. Required Forms (Assurance of Compliance Form, list of funding sources, etc.)

B. Key Staff Resumes

C. Signed Partnership MOAs

D. Program Timeline

E. Organization Chart

F. State Women's Health Coordinator Letter

G. Tables 1–9 in the Application Kit, if not included in the program narrative

H. Other Attachments

3. *Submission Dates and Times.* To be considered for review, applications must be received by the Office of Public Health and Science, Office of Grants Management, c/o WilDon Solutions, by 5 p.m. Eastern Time on the due date published in **DATES** section of the **Federal Register**. Applications will be considered as meeting the deadline if they are received on or before the deadline date. The application due date requirement in this announcement supersedes the instructions in Form OPHS–1.

Submission Mechanisms

The Office of Public Health and Science (OPHS) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OPHS Office of Grants Management after the deadlines described below will not be accepted for review. Applications which do not conform to the requirements of the grant announcement will not be accepted for review and will be returned to the applicant.

While applications are accepted in hard copy, the use of the electronic application submission capabilities provided by the GrantSolutions system or the Grants.gov Web site Portal is encouraged. Applications may only be submitted electronically via the electronic submission mechanisms specified below. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review.

Electronic grant application submissions must be submitted no later than 5 p.m. Eastern Time on the deadline date specified in the **DATES** section of the announcement using one of the electronic submission mechanisms specified below. All required hardcopy original signatures and mail-in items must be received by the OPHS Office of Grants Management, c/o WilDon Solutions no later than 5 p.m. Eastern Time on the next business day after the deadline date specified in the **DATES** section of the announcement.

Applications will not be considered valid until all electronic application components, hardcopy original signatures, and mail-in items are received by the OPHS Office of Grants Management according to the deadlines specified above. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process, and to submit early on the due date or before. This will aid in addressing any problems with submissions prior to the application deadline.

Electronic Submissions Via the Grants.gov Web Site Portal

The Grants.gov Web site Portal provides organizations with the ability to submit applications for OPHS grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system is available on the Grants.gov Web site: *http://www.grants.gov.*

In addition to electronically submitted materials, applicants may be required to submit hard copy signatures for certain Program related forms, or original materials as required by the announcement. It is imperative that the applicant review both the grant announcement, as well as the application guidance provided within the Grants.gov application package, to determine such requirements. Any required hard copy materials, or documents that require a signature, must be submitted separately via mail to the OPHS Office of Grants Management, c/o WilDon Solutions, and if required, must contain the original signature of an individual authorized to act for the applicant agency and the obligations imposed by the terms and conditions of the grant award. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Electronic applications submitted via the Grants.gov Website Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. All required mail-in items must be received by the due date requirements specified above. Mail-in items may only include publications, resumes, or organizational documentation. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Upon completion of a successful electronic application submission via the Grants.gov Website Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (Eastern

Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Web site Portal will be validated by Grants.gov. Any applications deemed ''Invalid'' by the Grants.gov Web site Portal will not be transferred to the GrantSolutions system, and OPHS has no responsibility for any application that is not validated and transferred to OPHS from the Grants.gov Website Portal. Grants.gov will notify the applicant regarding the application validation status. Once the application is successfully validated by the Grants.gov Web site Portal, applicants should immediately mail all required hard copy materials to the OPHS Office of Grants Management, c/o WilDon Solutions, to be received by the deadlines specified above. It is critical that the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard copy materials.

Once the application is validated by Grants.gov, it will be electronically transferred to the GrantSolutions system for processing. Upon receipt of both the electronic application from the Grants.gov Web site Portal, and the required hardcopy mail-in items, applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of the application submitted using the Grants.gov Web site Portal.

Applicants should contact Grants.gov regarding any questions or concerns regarding the electronic application process conducted through the Grants.gov Web site Portal.

Electronic Submissions Via the GrantSolutions System

The electronic grants management system, *http://www.GrantSolutions.gov,* provides for applications to be submitted electronically. When submitting applications via the GrantSolutions system, applicants are required to submit a hard copy of the application face page (Standard Form 424 included in Form OPHS–1) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program related forms (e.g., Program Certifications) with the original signature of an individual authorized to act for the applicant agency. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Electronic applications submitted via the GrantSolutions system must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail-in items to be sent to the Office of Grants Management separate from the electronic submission; however these mail-in items must be entered on the GrantSolutions Application Checklist at the time of electronic submission, and must be received by the due date requirements specified above. Mail-in items may only include publications, resumes, or organizational documentation. When submitting the required forms, do not send the entire application. Complete hard copy applications submitted after the electronic submission will not be considered for review.

Upon completion of a successful electronic application submission, the GrantSolutions system will provide the applicant with a confirmation page indicating the date and time (Eastern Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components, required hardcopy original signatures, and mail-in items, as well as the mailing address of the OPHS Office of Grants Management where all required hard copy materials must be submitted.

As items are received by the OPHS Office of Grants Management, the electronic application status will be updated to reflect the receipt of mail-in items. It is recommended that the applicant monitor the status of their application in the GrantSolutions system to ensure that all signatures and mail-in items are received.

Mailed or Hand-Delivered Hard Copy Applications

Applicants who submit applications in hard copy (via mail or hand-delivered) are required to submit an original and two copies of the application. The original application must be signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award.

Mailed or hand-delivered applications will be considered as meeting the deadline if they are received by the OPHS Office of Grant Management, c/o WilDon Solutions, on or before 5 p.m. Eastern Time on the deadline date specified in the **DATES** section of the announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the Form OPHS–1. Applications that do not meet the deadline will be returned to the applicant unread.

4. *Intergovernmental Review:* This program is subject to the Public Health Systems Reporting Requirements. Under these requirements, a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). Applicants shall submit a copy of the application face page (SF–424) and a one page summary of the project, called the Public Health System Impact Statement. The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based, non-governmental organizations within their jurisdictions.

Community-based, non-governmental applicants are required to submit, no later than the Federal due date for receipt of the application, the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted: (a) A copy of the face page of the application (SF 424), (b) a summary of the project (PHSIS), not to exceed one page, which provides: (1) A description of the population to be served, (2) a summary of the services to be provided, and (3) a description of the coordination planned with the appropriate state or local health agencies. Copies of the letters forwarding the PHSIS to these authorities must be contained in the application materials submitted to the OWH.

This program is also subject to the requirements of Executive Order 12372 that allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application kit to be made available under this notice will contain a listing of States that have chosen to set up a review system and will include a State Single Point of Contact (SPOC) in the State for review. Applicants (other than federally recognized Indian tribes) should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC in each affected State. A

complete list of SPOC may be found at the following Web site: *http://www.whitehouse.gov/omb/grants/spoc.html.* The due date for State process recommendations is 60 days after the application deadline. The OWH does not guarantee that it will accommodate or explain its responses to State process recommendations received after that date. (See ''Intergovernmental Review of Federal Programs,'' Executive Order 12372, and 45 CFR part 100 for a description of the review process and requirements.)

5. *Funding Restrictions:* Funds may not be used for construction, building alterations, equipment, printing, food, and medical treatment. All budget requests must be justified fully in terms of the proposed goals and objectives of the program and include an itemized computational explanation/breakout of how costs were determined.

6. *Other Submission Requirements:* As of October 1, 2003, all applicants are required to obtain a Data Universal Numbering System (DUNS) number as preparation for doing business electronically with the Federal Government. The DUNS number must be obtained prior to applying for OWH funds. The DUNS number is a nine-character identification code provided by the commercial company Dun & Bradstreet, and serves as a unique identifier of business entities. There is no charge for requesting a DUNS number, and you may register and obtain a DUNS number by either of the following methods:

Telephone: 1–866–705–5711.

Web site: *https://eupdate.dnb.com/requestOptions.html.*

Please note that registration via the Web site may take up to 30 business days to complete.

V. Application Review Information

Applications will be screened upon receipt. Those that are judged to be incomplete or arrive after the deadline will not be reviewed. Applications that are judged to be in compliance will be reviewed for technical merit by a technical review panel composed of experts with experience with sex and gender programs, program management, service delivery, outreach, health education, Healthy People 2000 and/or Healthy People 2010, leadership development, and program assessment in accordance with DHHS policies. Consideration for award will be given to applicants that best demonstrate progress and/or plausible strategies for eliminating health disparities through sex and gender targeted HP 2010 objectives. Applicants are also advised to pay close attention to the specific program guidelines and general instructions in the Application Kit.

1. *Criteria:* The technical review of applications will consider the following factors:

Factor 1: Background and Implementation Plan (30 Points)

To receive the maximum points for this Factor, the applicant must address all the items listed in the Background and Implementation Plan in Section IV. Application and Submission Information. At a minimum, the HP 2010 objectives selected must be stated clearly with baseline and target data for the objectives and for the population to be served. In addition, the overall program objectives must also be stated in SMART format. Using the example stated earlier, a SMART objective for Focus Area 12—Heart Disease and Stroke may be: In State X, the applicant will increase the number of Hispanic men age 35–50 who have their high blood pressure under control from x% to y% in three years by increasing the percent of Hispanic men with a usual primary care provider. The rationale for the selection of the objectives and the anticipated impact on the community, if the target is reached, must also be described. The rationale may be that several studies (provide references) show that uninsured people are less likely to have a regular source of care, less likely to receive preventive and primary care, less likely to receive required preventive services, and more likely to delay needed medical care than insured people. One activity of the evidence-based strategy (provide references) may be to use an Eligibility Specialist to help enroll these men in all social services programs for which they are eligible to assist them in receiving insurance coverage, or other financial support, to pay for needed care, thus increasing their chance of receiving the services needed to help control their blood pressure.

All applicants must achieve, at a minimum, the following three outcomes: establish a gender focus within the public health system/collaborative partnership, implement a surveillance/tracking system, and develop and implement a sustainability plan. Plans for achieving each of the overall program outcomes that should be included in the Implementation Plan, not just those listed above, must be described. Outcome measures, beyond process measures, must also be described along with plans to track and report HP 2010 and overall program outcomes. Applicants should also address their resources and ability to meet the tribal, county, State, or national HP 2010 targets. The baseline data for the individual HP 2010 objectives have been published by the National Center for Health Statistics and are available on the DATA2010 Web site located at *http://wonder.cdc.gov/data2010/.* States may have published their own HP 2010 data. The HP 2010 Midcourse Review assesses progress toward the Healthy People 2010 objectives at the mid-point of the decade and is available at *http://www.healthypeople.gov/Data/midcourse.* These data, along with the tribal, State, local, or county data should be used to develop a plan to measure the impact of additional resources on the applicant's ability to meet the HP 2010 targets. Applicants must provide a projection of their success (percent of targeted change achieved) without the additional support and a projection of their success with the additional support. A plan to objectively track and quantify progress toward target(s) annually must be included in the evaluation section of the grant application Factor 4.

Factor 2: Strength of the Public Health System/Collaborative Partnerships (Partnership Plan) (20 Points)

To receive the maximum points for this Factor, the applicant must address all the items listed in the Partnership Plan in Section IV. Application and Submission Information. At a minimum, the applicants must include a statement of the program goal(s) and objectives. The public health system/collaborative partnership, as a collective, must have demonstrated knowledge, experience, and resources to enhance their chance of reaching the national, State, county, or tribal HP 2010 targets for the objectives selected. The applicant must include a comprehensive description of the current public health system/collaborative partnership and describe how the public health system/collaborative partnership is presently addressing HP 2010 objectives and gender issues. A partnership plan that lists each partner, describes in detail the role of each partner, their strengths/expertise as it relates to the selected HP 2010 objectives, the experience of the person assigned as the liaison to the project, and the percent effort for the liaison to work on project activities must also be included in this section. The length of the formal relationship between the partners and applicant should be described. The partnership tables (Tables 5 and 8) must be used to present this information. The length of the collaboration may date back to a non-HP 2010 activity. Applicants are encouraged to include the State

Women's Health Coordinators (SWHCs) among their partners. A letter from the SWHC stating her willingness to participate in the system/collaborative partnership and her role on the project should be included in the Appendix.

Factor 3: Management Plan (20 Points)

To receive the maximum points for this Factor, the applicant must address all the items listed in the Management Plan in Section IV. Application and Submission Information. At a minimum, applicant organizations must describe their capability to manage the project as determined by the qualifications of the proposed staff; proposed staff level of effort; management experience of the staff; and the experience, resources, and role of each partner organization as it relates to program needs and activities. Resumes of key staff and partners should be included in the Appendix. Include the name, degrees earned, position, and FTE equivalent for each person/partner working on the program and listed in the Key Staff table. This table should provide enough information to identify the number of key personnel (salaried and in-kind) involved in the program (Table 9). Partners' liaison information should also be included in this chart. If the partners' liaison is different from the person serving on the Steering Committee, that individual's information should be included in this section. The Management Plan should also describe succession planning for key personnel and cross training of responsibilities. It should also include a description detailing how the resources of the partners and the applicant organization will be integrated to develop a comprehensive, integrated, multidisciplinary strategy to address the selected program and HP 2010 objectives.

Factor 4: Evaluation Plan (20 Points)

To receive the maximum points for this Factor, the applicant must address all the items listed in the Evaluation Plan in Section IV. Application and Submission Information. At a minimum, the applicant must provide a comprehensive description of how the program will be evaluated, especially as it relates to outcomes. This description should include a timeline, a discussion of data sources and how the data will be obtained and used. The OWH is particularly interested in tracking progress towards target(s). In addition, describe the impact of the additional resources on the public health system/collaborative partnership's ability to meet tribal, local, State, or national HP 2010 target(s) and how progress towards target(s) will be measured.

Factor 5: Sustainability Plan (10 Points)

To receive the maximum points for this Factor, the applicant must address all the items listed in the Sustainability Plan in Section IV. Application and Submission Information. The goals of sustaining the program may be: (1) To maintain the benefits achieved through the program, (2) to institutionalize the program within the parent-grant organization and among the partners, (3) to keep component(s) of the program operational after the OWH funding ends, or (4) others. At a minimum, the sustainability plan should describe how the program will be maintained after OWH funding ends and the benefit of the sustained program to the target population. The plan should also address anticipated long-range benefits to the community, tribe, region, State, and/or county. Thoughtful succession planning and cross training of responsibilities could contribute to the sustainability of the program. Describe succession planning and plans to cross train within individual organizations and across the public health system/collaborative partnership.

2. *Review and Selection Process:* Accepted applications will be reviewed for technical merit in accordance with DHHS policies. Applications will be evaluated by an objective/technical review panel composed of experts in the fields of public health systems, program management, academic/community service delivery, outreach, health education, women's health, men's health, Healthy People 2000/2010, and evaluation. Consideration for award will be given to applicants that meet the goals and review criteria of the ASIST2010 programs.

Funding decisions will be made by the OWH, and will take into consideration the recommendations and ratings of the review panel, program needs, stated preferences, the recommendations made based on the pre-award site visit, and the availability of Federal funds.

VI. Award Administration Information

1. *Award Notices:* Within a month of the review of all applications, applicants not scoring in the funding range will receive a letter stating that they have not been recommended for funding. Applicants scoring in the funding range will be contacted to schedule a pre-award site visit. Applicants selected for funding support will receive a Notice of Grant Award in September signed by the Grants Management Officer. This is the authorizing document to begin performing grant activities and it will be sent electronically and followed up with a mailed copy. Pre-award costs are not supported by the OWH.

2. *Administrative and National Policy Requirements:* (1) In accepting this award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of the 45 CFR parts 74 and 92, currently in effect or implemented during the period of this grant. (2) Requests that require prior approval from the awarding office (See Chapter 8, PHS Grants Policy Statement) must be submitted in writing to the OPHS Grants Management Office. Only responses signed by the Grants Management Officer are to be considered valid. Grantees who take action on the basis of responses from other officials do so at their own risk. Such responses will not be considered binding by or upon the OWH. (3) Responses to reporting requirements, conditions, and requests for post-award amendments must be mailed to the Office of Grants Management at the address indicated below in ''Agency Contacts.'' All correspondence requires the signature of an authorized business official and/or the project director. Failure to follow this guidance will result in a delay in responding to your correspondence. (4) The DHHS Appropriations Act requires that, when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, the issuance shall clearly state the percentage and dollar amount of the total costs of the program or project that will be financed with Federal money and the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

3. *Reporting.* A successful applicant will submit a quarterly progress report on December 10, March 10, June 10, and August 10, and a Financial Status Report 90 days after the close of each 12-month budget period. The June 10 report will serve as the non-competing renewal application. An original and two copies of the non-competing renewal application must be submitted no later than June 10 and report on program activities from September through the end of May. The final progress report is due 30 days after the close of the project period (August 31, 2010). If a submission date falls on a Saturday or Sunday, then the report will be due the following Monday.

The non-competing renewal application must include a discussion of progress made on the grant during the

year, plans for the coming year, a budget request for the next grant year, with complete justification, and appropriate signatures, and be submitted using Form OPHS–1. A Financial Status Report (FSR) SF–269 is due 90 days after the close of each 12-month budget period. A copy of the form will be sent with the Notice of Grant Award.

VII. Agency Contact(s)

For Application Kits, submission of applications, and information on budget and business aspects of the application, please contact: WilDon Solutions, Office of Grants Management Operations Center, 1515 Wilson Boulevard, Third Floor Suite 310, Arlington, VA 22209 at 1–888–203–6161, e-mail *OPHSgrantinfo@teamwildon.com,* or fax 703–351–1138. Also contact Wildon Solutions with questions regarding programmatic information and/or requests for technical assistance in the preparation of the grant application.

VIII. Other Information

Not applicable.

Dated: April 13, 2007.

Wanda K. Jones,

Deputy Assistant Secretary for Health (Women's Health), Office of Public Health and Science.

[FR Doc. E7–7371 Filed 4–17–07; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public on both Thursday, May 10 and Friday, May 11, 2007.

DATES: The meeting will take place Thursday, May 10, 2007 and Friday, May 11, 2007 from 9 a.m. to 5 p.m.

ADDRESSES: Georgetown University Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

FOR FURTHER INFORMATION CONTACT: Jerry A. Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Room 250, Rockville, MD 20852, (240) 453–8803, FAX (240) 453–8456, e-mail *ACBSA@hhs.gov.*

SUPPLEMENTARY INFORMATION: The ACBSA will receive updates on previous recommendations to include variant Creutzfeldt Jacob Disease (vCJD), Chagas, Transfusion Related Acute Lung Injury (TRALI) and West Nile Virus.

Since the last meeting, the Committee's Charter was modified and approved by Secretary Leavitt in October 2006 to include broad public health, ethical and legal issues related to transfusion and transplantation safety. In order to understand these areas of commonality, the main topic of this meeting will center on presentations and discussion of common concerns in transfusion and transplantation safety.

The new charter permits the expansion of the Committee ex-officio members to include agencies other than those currently having a permanent ex-officio seat. Representation from the Division of Organ Transplantation within the Health Resources and Services Administration (HRSA) and the Office of Cellular, Tissue, and Gene Therapy within the Food and Drug Administration (FDA) will be added as Committee ex-officio members.

Public comment will be solicited on Thursday, May 10, at noon and Friday, May 11, before noon. Comments will be limited to five minutes per speaker. Anyone planning to comment is encouraged to contact the Executive Secretary at his/her earliest convenience. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business May 7, 2007. Likewise, those who wish to utilize electronic data projection to the Committee must submit their materials to the Executive Secretary prior to close of business May 7, 2007.

Dated: April 13, 2007.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E7–7340 Filed 4–17–07; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Adopting and Demonstrating the Adaptation of Prevention Techniques for Persons at Highest Risk of Acquiring or Transmitting Human Immunodeficiency Virus (ADAPT2), Funding Opportunity Announcement (FOA) Number PS07–004

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting of the aforementioned Special Emphasis Panel.

Time and Date:

8:30 a.m.–9 a.m., May 18, 2007 (Open).

9 a.m.–4 p.m., May 18, 2007 (Closed).

Place: Sheraton Midtown Atlanta Hotel at Colony Square, 188 14th Street, Atlanta, GA 30361.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of a research application in response to FOA PS07–004, ''Adopting and Demonstrating the Adaptation of Prevention Techniques for Persons at Highest Risk of Acquiring or Transmitting Human Immunodeficiency Virus (ADAPT2).''

Contact Person For More Information: J. Felix Rogers, M.P.H., PhD, Scientific Review Administrator, Extramural Research Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E05, Atlanta, GA 30333, telephone 404.639.6101.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 10, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–7331 Filed 4–13–07; 10:39 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel ''Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (Panel 7),'' Request for Application Number (RFA) DP07–002

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting of the aforementioned Special Emphasis Panel.

Time and Date: 12 p.m.–4 p.m., June 5, 2007 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of research grant applications received in response to RFA DP07–002, ''Health Promotion and Disease Prevention Research Centers: Special Interest Project Competitive Supplements (Panel 7).''

Contact Person for More Information: Sheree Marshall Williams, PhD, M.Sc., Scientific Review Administrator, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS D72, Atlanta, GA 30333, telephone 404.639.4896.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 10, 2007.

Elaine L. Baker

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–7332 Filed 4–17–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control Initial Review Group (NCIPC/IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meetings of the aforementioned committee:

Times and Dates:

2 p.m.–5 p.m., May 14, 2007 (Closed).
2 p.m.–5 p.m., May 15, 2007 (Closed).
2 p.m.–5 p.m., May 16, 2007 (Closed).
2 p.m.–5 p.m., May 17, 2007 (Closed).
2 p.m.–5 p.m., May 18, 2007 (Closed).

Place: The conference calls will originate at the Centers for Disease Control and Prevention, Vanderbilt Building, Koger Center, Atlanta, Georgia.

Times and Dates:

9 a.m.–10 a.m., May 21, 2007 (Open).
10 a.m.–5 p.m., May 21, 2007 (Closed).
9 a.m.–3 p.m., May 22, 2007 (Closed).
3 p.m.–5 p.m., May 22, 2007 (Open).
5 p.m.–7 p.m., May 22, 2007 (Closed).
9 a.m.–5:30 p.m., May 23, 2007 (Closed).
9 a.m.–5 p.m., May 24, 2007 (Closed).

Place: Sheraton Midtown Atlanta Hotel Colony Square, Atlanta, Georgia.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of individual research grant and cooperative agreement applications submitted in response to two Fiscal Year 2007 Requests for Applications related to the following individual research announcements: 07002, Family and Dyadic Focused Interventions to Prevent Intimate Partner Violence; 07003, Maximizing Protective Factors for Youth Violence; 07004, Abusive Head Trauma (AHT) Prevention; 07005, Understanding Bullying and Sexual Violence Perpetration and Factors Associated with Both Outcomes; 07006, Grants for Traumatic Injury Biomechanics Research; 07007, Dissemination Research on Fall Prevention: ''Stepping On'' in a U.S. Community Setting; and 07008, The Impact of Traumatic Brain Injury Among Incarcerated Persons.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jane Suen, PhD, NCIPC/IRG, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341–3724, telephone 770/488–1240.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 10, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–7339 Filed 4–17–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1080, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 72 FR 14578, dated March 28, 2007) is amended to reflect the reorganization of the Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the mission statements for the *Coordinating Center for Infectious Diseases (CV) and the Office of the Director (CVA),* and insert the following:

Coordinating Center for Infectious Diseases (CV). The mission of the Coordinating Center for Infectious Diseases (CCID) is to protect health and enhance the potential for full, satisfying, and productive living across the lifespan of all people in all communities related to infectious diseases. To carry out its mission, CCID: (1) Fosters collaborations across CID's centers, divisions and branches, builds external and internal partnerships, supports both science and program integration, and leverages both human and budgetary resources to increase the Centers for Disease Control and Prevention's (CDC) health impact and achieve population health goals; (2) helps investigate and diagnose infectious diseases of public health significance; (3) coordinates applied and operational research to define, prevent, and control infectious diseases; (4) assists in providing consultation and training to help state and local health departments plan, develop, implement, and improve immunization programs; (5) coordinates research and operational programs to prevent and control vaccine preventable diseases; and (6) assists in providing technical assistance to states, localities, and other nations to investigate and diagnose sexually transmitted diseases (STDs), viral hepatitis, tuberculosis (TB), human immunodeficiency virus (HIV) infections, and retroviruses; and coordinates applied and operational research on the spread, diagnosis, prevention, and control of HIV, other STDs, viral hepatitis, TB, and non-TB mycobacteria, and non-HIV retroviruses.

Office of the Director (CVS). (1) Manages, coordinates, and evaluates the activities of the CCID; (2) communicates overarching goals and objectives, and provides leadership, scientific oversight, and guidance in program planning and development; (3) coordinates assistance provided by CCID to other CDC components, other federal, state, and local agencies, the private sector, and other nations; (4) provides and coordinates resource management support services for CCID; (5) manages and coordinates workforce development and succession planning activities within CCID in collaboration with internal and external partners, and coordinates the recruitment, assignment, technical supervision, and career development of staff with emphasis on developing and supporting diversity initiatives and equal opportunity goals; (6) assists in communication activities; (7) fosters collaboration of cross-cutting CCID scientific and programmatic issues through the Strategic Science and Program Unit; and (8) ensures consistent, efficient, and effective administration of mission support functions through the establishment and management of the Strategic Business Unit.

Strategic Business Unit (CVA2). The mission of the Strategic Business Unit (SBU) is to support CCID programs and staff through the efficient, professional, and timely delivery of critical public health mission-support services. In carrying out its mission, the SBU performs the following functions: (1) Provides direct and daily management and execution of domestic travel processing for federal employees, Commissioned Corps, and all CDC-invited guests; (2) provides direct and daily management and execution of the administrative aspects of human resources across CCID, including training and administration of policies and guidelines developed by the Atlanta Human Resources Center, Department of Health and Human Services (HHS), Ethics Office, Financial Management Office (FMO), Office of Commissioned Corps Personnel, Coordinating Office for Global Health (COGH), Office of Personnel Management, Office of Workforce and Career Development, and Procurement and Grants Office (PGO); (3) provides direct and daily management and execution of the coordination of laboratory and office facilities, and supplies technical guidance and expertise regarding occupancy and facilities management to emergency situations, CDC; (4) provides direct and daily management and execution of the distribution, accountability, and maintenance of CDC property and equipment; (5) provides direct and daily management and execution of the creation, organization, access, maintenance, and disposition of CCID records, and of the establishment of policies and procedures coordinating a CCID response to Freedom of Information Act (FOIA) requests; and (6) provides direct and daily management and execution of the coordination of logistics for CCID's federal government committee meetings and conferences.

Travel (CVA22). (1) Prepares for approval travel requests, travel orders, vouchers for reimbursement, in-kind, reimbursable, relocation services, and permissive travel documentation for domestic travel; (2) administers and provides oversight for travel cards; follows up with audits; communicates with national centers (NC) regarding possible fraud, delinquencies, and abuses; troubleshoots for lost or stolen cards; and, generates related reports; (3) provides emergency travel support in response to emergencies, outbreaks, and domestic incidents; (4) prepares group travel memos to HHS for meetings in excess of 20 attendees (meetings), conferences in excess of 99 attendees, actual expense memos, premium class (medical) memos, and cash purchase memos; and (5) provides guidance and expertise pertaining to travel.

Personnel/Training (CVA23). (1) Processes security clearance forms, ID badges, and card keys for FTEs and non-FTEs; (2) performs administrative aspects of recruitment, retention and promotion; (3) manages administrative functions related to employee performance (EPMS, ceremonies, awards, promotions); (4) manages administrative functions related to Commissioned Corps; (5) serves as point of contact for payroll issues including time/attendance records, executive pay appointments, bonuses/allowances, and other special pay agreements; (6) manages administrative functions for non-CDC employees including ORISE fellows, Student Temporary Employment Program, contractors, guest researchers, and interagency agreements (IAA); (7) performs administrative functions related to staffing and other human resource issues including employee relations, FTE tracking, on-board strength reports, PeopleSoft Access, WIZ data and staffing lists, individual development plans (IDP), and individual learning accounts (ILA); manages IDP/ILA accounts and tracks completion of IDPs; (8) enters training requests into mainframe and forwards requests to appropriate channels for approval; (9) verifies requested training is on IDP; (10) tracks scheduling and completion of CDC-required training courses; (11) maintains accurate training log in mainframe; (12) tracks and prints certifications for staff that have completed training courses; (13) manages vendor registration process and initiates payment process for vendors who provide training; and (14) assists with scheduling CCID employees for Corporate University courses.

Procurement/Property/Facilities (CVA24). (1) Processes purchase orders, requisitions, and contracts using ICE; (2) processes credit card transactions for purchases <$2,500 using MACCS; (3) manages receiving and acceptance for both ICE and Visa orders; (4) serves as liaison with CCID lead to respond to ICE inquiries; (5) performs administrative tasks related to initiating, processing, and maintaining IAA; (6) processes contract invoices and payments; (7) reviews and approves all issues and requests related to office and laboratory space; (8) serves as liaison with programs and other necessary parties (Buildings and Facilities Office, Office

of Health and Safety (OHS), Office of Security and Emergency Response (OSEP), Real Properties Office, etc.) to oversee the implementation of all approved requests; (9) coordinates funding for facilities projects; (10) works closely with OSEP and Physical Security to coordinate, approve, and monitor access to restricted high security laboratory buildings and select agent laboratories; (11) serves as liaison with architects and engineers regarding construction projects; (12) provides scientific and technical guidance, and coordination of resources during emergency operations; (13) serves on CDC Emergency Response Team subcommittee; (14) accounts for CDC property (computers, laptops, cell phones, Blackberries, etc.) and laboratory equipment; (15) tracks repairs, losses, and maintenance agreements; (16) facilitates acquisition replacement parts; (17) serves as liaison to the Information Technology Services Office for technical approval of information technology (IT) related purchases; (18) coordinates with appropriate parties to access and distribute property and equipment; (19) coordinates annual inventory process; and (20) purchases, maintains, and checks-out/-in barcode scanners for use by programs for annual inventory.

Records Management/FOIA/Committee/Management/Conference Logistics (CVA25). (1) Responsible for physical transfer of files to Federal Records Center (pack boxes, record contents, transfer boxes to courier); (2) organizes and classifies files throughout the organization; (3) maintains and staffs file stations throughout the organization; (4) assists the CDC Records Officer in the development of records management schedules; (5) receives and interprets requests directly from CDC FOIA office; (6) checks for similar and/or duplicate requests; (7) performs preliminary work (scanning, copying); (8) creates and maintains files in the FOIA log; (9) disburses requests to center/division/programs (CDP); (10) sends time-sensitive reminders to CDP liaisons and others working on request; (11) receives completed responses from programs; (12) evaluates information and works with the CDC FOIA Office and program coordinators to ensure that all response packages are complete and within the scope of the request; (13) performs secondary review for identifying possibly exempt material; (14) serves as liaison with CDC FOIA Office and CDC Office of General Counsel for complex requests; (15) sends all responses to CDC FOIA Office for final review; (16) works with records management group to develop and adhere to a uniform record retention policy regarding FOIA requests; (17) conducts training for scientists and program staff on FOIA exemptions and response process; (18) initiates all personnel actions for CCID committee members; (19) coordinates meeting logistics, travel arrangements, production and distribution of materials, and preparation and distribution of meeting transcripts; (20) maintains agendas, minutes, records, reports and transcripts; (21) records action items and provides feedback to the committees via written and electronic correspondence; (22) prepares standardized committee reports for Government Services Agency, HHS, and the Management Analysis and Services Office (MASO); (23) finalizes nominee packages for CCID committees; (24) coordinates contractor support; (25) prepares and assembles technical proposal packages; (26) coordinates administrative requirements to ensure abstract review/approval by appropriate program and scientific staff; (27) processes conference facility and support contracts; (28) finalizes memorandums of understanding, obtain legal clearance as needed, and maintains records; (29) supports conference registration procedures as needed; (30) coordinates communications to committee members, speakers, and attendees as directed by programmatic personnel; (31) processes orders and payments of print and non-print conference materials; (32) assembles conference materials; (33) coordinates follow-up with invited participants; (34) coordinates ordering and shipment of conference supplies to be used on-site; and (35) coordinates on-site conference administrative staffing support.

Strategic Science and Program Unit (CVA3). The mission of the Strategic Science and Program Unit (SSPU) is to provide scientific and laboratory services to stakeholders across CCID. In carrying out its mission, the SSPU: (1) Ensures process consistency for science and laboratory related functions across the NCs; (2) facilitates cross-center decision-making regarding science and laboratory activities; (3) facilitates communication regarding scientific and programmatic services across CCID; (4) develops and administers, in collaboration with CCID's divisions/programs/offices, requests for applications and program announcements for extramural research; (5) serves as the focal point for implementing policies and guidelines for the conduct of the peer review of extramural research grant proposals and subsequent grant administration; (6) monitors the performance of funded extramural research projects in the areas of infectious diseases and immunization; (7) conducts necessary regulatory and ethical reviews for activities involving human participants, including determining whether an activity includes research, includes human subjects, is exempt or requires Institutional Review Board (IRB) approval, and whether an exception is needed to the Public Health Service (PHS) HIV policy; (8) reviews funded activities for application of human research regulations; completes PGO tracking forms for Funding Opportunity Announcements and contracts; (9) reviews, approves, and tracks research protocols, clinical investigations, and the Food and Drug Administration (FDA) regulated response activities intended for submission to CDC Human Research Protections Office; (10) coordinates and tracks Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act; (11) serves as authorized representative to/from FDA on all CDC Investigational New Drug (IND) protocols, Investigational Device Exemption applications, 510(k) applications, pre-Emergency Use Authorization (EUA) requests, and Drug Master File submissions; (12) centralizes and standardizes all CDC/FDA official correspondences; (13) drafts, reviews, prepares, and tracks all IND Protocols regulated by 21 CFR 312 and all pre-EUA documents; (14) develops and maintains standard operating procedures (SOP) and templates for processing non-research actions through the NCs to PGO; (15) monitors changes in grants management policies and procedures and adjusts SOPs as necessary; (16) liaises with PGO regarding general policies, procedures and forecasting; (17) organizes and coordinates logistics for panel reviews for non-research programs; (18) receives and reviews research proposals and initiates contact with technology transfer specialist; (19) negotiates terms of agreements with external parties; (20) reviews patent/intellectual property issues and potential conflicts of interest; (21) liaises with CCID organizations to advise, plan, coordinate, implement, manage, and oversee the allocation of additional or alternate laboratory, laboratory support, and laboratory office space; (22) plans and advises relocation into existing buildings and newly acquired laboratory, lab office, and lab support space; (23) serves as advisor to CCID management on issues of safety,

including biosafety, chemical safety, and radiation safety; (24) serves as the principal liaison to the OHS; (25) coordinates CCID safety program, working with all levels of CCID safety committees; and (26) monitors safety survey process and findings and ensures that all deficiencies are addressed in timely manner (remediation).

Informatics (CVA33). The mission of the CCID Informatics is to maximize the capacity for information technology to enhance the efficacy of infectious disease prevention. In carrying out its mission, Informatics: (1) Manages all IT project costs, schedules, performances, and risks; (2) provides expertise in leading application development techniques in information science and technology to effect the best use of resources; (3) performs technical evaluation and/or integrated baseline reviews of all information systems' products and services prior to procurement to ensure software purchases align with CCID strategy; (4) provides access to quality data in support of programmatic data analysis; (5) coordinates all enterprise-wide IT security policies and procedures with the office of the CDC Chief Information Security Officer; (6) ensures operations are in accordance with CDC Capital Planning and Investment Control guidelines; (7) ensures adherence to CDC enterprise architecture guidelines and standards; (8) consults with users to determine IT needs and to develop strategic and action plans; and (9) participates in the evolution, identification, development, or adoption of appropriate informatics standards in conjunction with the Coordinating Center for Health Information and Service.

Enterprise Communications (CVA32). The mission of the CCID Enterprise Communications (EC) is to lead CCID's support of the CDC Office of Enterprise Communication (OEC) in promoting public health and preventing disease through coordination and prompt response to urgent issues and concerns; recognition of issues requiring establishment or reevaluation of agency positions; safeguarding CCID and CDC credibility with, and confidence of, employees, partners and public; promotion and maintenance of effective and efficient communication networks. In carrying out its mission, CCID EC: (1) Organizes, develops, and implements employee communication activities; develops, writes, edits, and publishes articles about CCID employees and their work through a variety of channels; (2) provides channels for publicizing employee achievements and awards, program accomplishments, and introducing new staff and management; (3) provides the central point of contact to CCID for the CCID Intranet; (4) provides a central point of reference for CCID announcements; (5) coordinates review and clearance of materials to be posted on CCID Intranet; (6) provides leadership in the development and branding of CCID's Intranet sites/pages; (7) assists the CCID and NC leadership in meeting their employee communication needs and priorities; (8) creates and maintains liaison with the CDC OEC, CDC Connects, and CCID NCs to share relevant employee communications information; (9) provides opportunities for two-way CCID employee communication, and timely and appropriate responses to inquiries and feedback from CCID employees; (10) conducts special projects as appropriate to develop feature CCID employee stories; (11) conducts employee research to enhance and improve CCID employee communication efforts including the CCID Intranet and other channels of employee communication; (12) provides employees access to information, services, activities, and materials that support or promote their health, morale, work efficiency, and sense of community; (13) serves as point of contact for controlled correspondence and other documents that require approval from the CCID Director and various other officials; (14) manages the flow of decision documents and correspondence for action by the CCID and NC directors; (15) coordinates collection and electronic management of CCID NC issues management materials; (16) ensures consistent application of CDC correspondence standards and styles; (17) coordinates CCID very important persons (VIP) visits and CCID lab tours for VIP visitors; (18) coordinates compilation of regularly updated CCID NC reports containing information on upcoming publications, activities, and other issues related to potential media opportunities, and CDC/ATSDR weekly legislative report for dissemination to CCID executive leadership team, CDC OEC, Coordinating Centers/Coordinating Offices (CC/CO), and NCs; (19) coordinates collection and electronic management of CCID and CCID NC issues management materials to include talking points, position papers, and others; (20) assists CCID NCs in meeting their press-related needs and priorities and provides or coordinates media training and technical assistance to CCID staff; (21) provides a central point of contact to CDC Division of Media Relations for CCID related media requests and manages electronic files; and (22) provides a central point for CCID media monitoring.

National Center for Immunization and Respiratory Diseases (CVG). The National Center for Immunization and Respiratory Diseases (NCIRD) prevents disease, disability, and death through immunization and by control of respiratory and related diseases. In carrying outs its mission, NCIRD: (1) Provides leadership, expertise, and service in laboratory and epidemiological sciences, and in immunization program delivery; (2) conducts applied research on disease prevention and control; (3) translates research findings into public health policies and practices; (4) provides diagnostic and reference laboratory services to relevant partners; (5) conducts surveillance and research to determine disease distribution, determinants, and burden nationally and internationally; (6) responds to disease outbreaks domestically and abroad; (7) ensures that public health decisions are made objectively and based upon the highest quality of scientific data; (8) provides technical expertise, education, and training to domestic and international partners; (9) provides leadership to internal and external partners for establishing and maintaining immunization, and other prevention and control programs; (10) develops, implements, and evaluates domestic and international public health policies; (11) communicates information to increase awareness, knowledge, and understanding of public health issues domestically and internationally, and to promote effective immunization programs; (12) aligns the national center focus with the overall strategic goals of CDC; and (13) implements, coordinates, and evaluates programs across NCIRD, CCID, and CDC to optimize public health impact.

Office of the Director (CVG). (1) Provides leadership, expertise, and service in laboratory and epidemiological sciences and in immunization program delivery; (2) provides diagnostic and reference laboratory services to relevant partnerships; (3) works with CCID OD to ensure spending plans, budget planning, and budget execution are in line with the overall infectious disease strategies and priorities; (4) ensures that the CCID strategy is executed by the divisions and aligned with overall CDC goals; (5) co-develops execution strategies for the center with the division directors; (6) provides program and science quality oversight; (7) builds leadership at the division and branch levels; (8) evaluates the strategies, focus, and prioritization

of the division research, program, and budget activities; (9) identifies and coordinates synergies between center and relevant partners; (10) ensures that policy development is consistent and appropriate; (11) facilitates research and program activities by providing leadership support; (12) proposes resource priorities throughout the budget cycle; (13) ensures scientific quality, ethics, and regulatory compliance; (14) fosters an integrated approach to research, program, and policy activities; (15) liaises with HHS and other domestic and international immunization and respiratory disease partners as well as with NCIRD divisions; and (16) coordinates center's emergency response activities related to immunization issues and complex acute respiratory infectious disease emergencies.

National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CVH). The National Center for Zoonotic, Vector-Borne, and Enteric Diseases (NCZVED) maximizes public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by suspected and confirmed zoonotic, vector-borne, foodborne, waterborne, mycotic, prion, and related infections. In carrying out its mission, NCZVED: (1) Provides leadership, expertise, and service in laboratory, medical, and epidemiological sciences throughout the world; (2) conducts applied research aimed to eliminate, prevent, and control disease; (3) translates research findings into public health policies, practices, and programs; (4) provides diagnostic and reference laboratory services to relevant partners; (5) conducts surveillance and research to determine disease distribution, disease determinants, and disease burden nationally and internationally; (6) responds to disease outbreaks domestically and abroad; (7) ensures that public health decisions are made objectively and based upon the highest quality of scientific data; (8) provides technical expertise, education, and training to domestic and international partners; (9) provides leadership to internal and external partners for establishing and maintaining screening, treatment, and other elimination, prevention, and control programs; (10) develops, implements, and evaluates domestic and international public health policies, practices, and programs; (11) communicates information to increase awareness, knowledge, and understanding of public health issues domestically and internationally; (12) aligns the national center focus with the overall strategic goals of the CDC; (13) implements, coordinates, and evaluates programs across CDC, CCID, and NCZVED to optimize public health impact; (14) conducts bioterrorism preparedness activities to prevent or lessen the severity of bioterrorism incidents; (15) builds strategic partnerships with internal and external stakeholders; and (16) clarifies the dynamic link between animals, people, and the environment to maximize public health impact.

Office of the Director (CVH1). (1) Works with CCID OD to ensure spending plans, budget planning, and budget execution are in line with the overall CDC infectious disease strategies and priorities; (2) ensures that the CCID strategy is executed by the divisions and aligned with overall CDC goals; (3) co-develops execution strategies for the national center with the division directors; (4) provides program and science quality oversight; (5) builds leadership at the division and branch levels; (6) evaluates the strategies, focus, and prioritization of the division research, program, and budget activities; (7) identifies and coordinates synergies between the national center and relevant partners; (8) ensures that policy development is consistent and appropriate; (9) facilitates research and program activities by providing leadership support; (10) proposes resource priorities throughout the budget cycle; (11) ensures scientific quality, ethics, and regulatory compliance; (12) fosters an integrated approach to research, program, and policy activities; (13) liaises with HHS and partners concerning activities related to vector-borne, zoonotic, and enteric infectious diseases; and (14) ensures that programmatic goals are achieved with measurable impact.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CVJ). The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) maximizes public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by Human Immunodeficiency Virus Infection/Acquired Immunodeficiency Syndrome (HIV/AIDS), non-HIV retroviruses, viral hepatitis, other STDs, TB, and non-tuberculosis mycobacteria. In carrying out its mission, NCHHSTP: (1) Builds capacity and enhances public health infrastructure for preventing and treating HIV/AIDS, viral hepatitis, STDs, and TB domestically and internationally; (2) coordinates activities and programs across CDC and CCID in order to maximize the public health impact of HIV/AIDS, viral hepatitis, STDs, and TB interventions; (3) conducts surveillance and research to determine the distribution, determinants, and burden of HIV/AIDS, viral hepatitis, STDs, and TB infections domestically and internationally; (4) conducts program evaluation to improve programs and activities relating to the prevention of HIV/AIDS, viral hepatitis, STDs, and TB, and determine their impact; (5) provides reference laboratory and clinical diagnostic services for HIV/AIDS, viral hepatitis, STDs, and TB to relevant stakeholders; (6) maximizes synergies among HIV/AIDS, viral hepatitis, STDs, and TB programs; domestically and internationally; (7) engages external partners to develop and implement effective HIV/AIDS, viral hepatitis, STDs, and TB policies, research, and programs; (8) engages partners to reduce health disparities among those affected by HIV/AIDS, viral hepatitis, STDs, and TB; (9) provides technical assistance and training to domestic and international partners in the diagnosis, treatment, and prevention of HIV/AIDS, viral hepatitis, STDs, and TB; (10) conducts domestic and international public health communication activities to disseminate research findings and increase awareness of HIV/AIDS, viral hepatitis, STDs, and TB; (11) conducts operational, behavioral, and biomedical research to improve the distribution, diagnosis, prevention, and control of HIV/AIDS, viral hepatitis, STDs, and TB; (12) provides scientific leadership regarding public health ethics and protection of human subjects linked to HIV/AIDS, viral hepatitis, STDs, and TB; (13) translates research findings into public health practice and policy for HIV/AIDS, viral hepatitis, STDs, and TB; (14) plans, coordinates, and guides programs and activities with external partners, federal agencies, and other organizations related to HIV/AIDS, viral hepatitis, STDs, and TB prevention, care, and treatment; (15) leads and participates in the development, implementation, and evaluation of domestic and international policies and guidelines related to HIV/AIDS, viral hepatitis, STDs, and TB; (16) provides scientific leadership regarding screening, treatment, immunization, and other prevention interventions relevant to HIV/AIDS, viral hepatitis, STDs, and TB; (17) assures all public health decisions are based on the highest quality scientific data, openly and objectively derived; (18) provides leadership to assist international partners in establishing and maintaining HIV/AIDS, viral hepatitis, STDs, and TB

screening, treatment, immunization, and other prevention and control programs; (19) assists countries in improving treatment, care, and support for people living with HIV/AIDS, and building capacity and infrastructure to address the global HIV/AIDS pandemic; (20) works with other federal agencies, governments of other nations, and other partners to implement the U.S. Government's international efforts to reduce the global burden of HIV/AIDS; (21) ensures that programmatic and scientific activities are aligned with, and in support of, CDC's overall mission, goals, and strategic imperatives; (22) allocates and tracks CDC resources and contributes to the development of CDC's short-, medium- and long-term strategic plans for preventing the spread of HIV/AIDS, viral hepatitis, STDs, and TB domestically and internationally; and (23) coordinates oversight of the NCHHSTP Federal Advisory Committees.

Office of the Director (CVJ1). (1) Provides leadership and guidance on the development of goals and objectives, policies, program planning and development, and program management and operations of the activities of the NCHHSTP, and manages, directs, coordinates, and evaluates the center's activities; (2) facilitates closer linkages between HIV, non-HIV retroviruses, STDs, viral hepatitis, TB, and non-TB mycobacteria surveillance activities and prevention programs at all levels, and facilitates collaboration, integration, and multi-disciplinary approaches to enhance the effectiveness of HIV, STD, viral hepatitis, and TB prevention programs; (3) facilitates integration of science and prevention programs throughout NCHHSTP and enhances the coordination and integration of HIV, STD, viral hepatitis, and TB prevention services for individuals and populations at increased risk for more than one of these infections; (4) coordinates the integration of CDC funding of state and local health departments for HIV, STD, viral hepatitis, and TB prevention; (5) facilitates and coordinates the assignment of field staff in accordance with CDC and NCHHSTP priorities and objectives; (6) provides technical information services to facilitate dissemination of relevant public health information and facilitates collaboration with national health activities, CDC components, other agencies and organizations, and foreign governments on international health activities; (7) provides oversight for the programmatic coordination of HIV, STD, viral hepatitis, and TB activities between NCHHSTP and other NCs; develops recommendations to the CDC Director as the lead NC for these programs for the distribution of HIV, STD, viral hepatitis, and TB funds CDC-wide; and advises the Director, CDC, on other policy matters concerning NCHHSTP activities; (8) provides technical assistance to divisions on issues management, public affairs, and health communications strategies, and coordinates with external organizations, the news, public service, entertainment and other media to ensure effective findings and their implications for public health reach the public; (9) collaborates closely with divisions to produce materials designed for use by the news media; (10) secures appropriate clearance of these materials within NCHHSTP and CDC; (11) develops strategies and operational systems for the proactive dissemination of effective findings and their implications for prevention partners and the public, responds to public inquiries, and distributes information materials apart from the clearinghouses, hotlines, or other contractual mechanisms; (12) coordinates graphics and publishing services for NCHHSTP staff; reviews and prepares congressional testimony and briefing documents; and analyzes the implications of legislation and legislative proposals; (13) plans and coordinates the annual program planning process; (14) coordinates with OD, CC/COs, and divisions in determining and interpreting operating policy and in ensuring their respective management input for specific program activity plans; (15) interprets general policy directives and proposed legislation relating to NCHHSTP program goals and objectives, and coordinates the development and review of congressional reports; serves as the coordination point for Inspector General and General Accounting Office audits and reviews; (16) coordinates and manages external groups such as advisory committees and serves as central point for OMB clearances and controlled correspondence; (17) advises on activities that might affect other NC and provides leadership in the integration of health disparities goals, objectives, and strategies in the development of policies and programs of NCHHSTP; (18) coordinates and tracks health disparity activities within the center and provides leadership in support of research, surveillance, education, training, and program development to reduce health disparities; (19) develops partnerships with other federal agencies and nongovernmental organizations working on similarly-affected populations; (20) provides technical support and funding to the Tuskegee University National Center for Bioethics in Research and Health Care and manages the Tuskegee Participants Health Benefits Program; (21) sponsors workgroups, meetings, and conferences related to health disparities and collaborates with the CDC Office of the Director, CC/COs, and other NCs on health disparity activities; (22) works with NCHHSTP leadership to promote a diverse public health workforce through internships, fellowships, training programs, and other activities; and (23) works with the CDC Office of Minority Health and Health Disparities to monitor progress in meeting the four Executive Orders related to improving minority health.

National Center for Preparedness, Detection, and Control of Infectious Diseases (CVK). The National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID) maximizes prevention, preparedness, and response to infectious diseases in order to protect populations domestically and internationally through leadership, partnerships, epidemiologic and laboratory studies, and the use of quality systems, standards, and practices. In carrying out its mission, NCPDCID: (1) Works collaboratively across CDC and with public health and healthcare partners in conducting, coordinating, and supporting surveillance, research, and prevention programs to prevent and minimize morbidity and mortality among domestic and international populations; (2) collaborates with other CDC programs to ensure availability of appropriate domestic and international platforms intended to build capacity and conduct public health work on infectious diseases; (3) coordinates activities across CCID and CDC related to vulnerable populations, healthcare quality, quarantine, research, surveillance, emerging infectious diseases, and laboratory services; (4) establishes relationships and partnerships with domestic and international health organizations, healthcare facilities, federal agencies, state and local health departments, and other external partners; (5) provides technical assistance to external partnerships for improving program operations; (6) provides a platform for synthesis, translation, and dissemination of research findings into public health practice at the front line; (7) participates in the development of national policies and guidelines for prevention and control of infectious diseases; (8) coordinates processes for developing, awarding, and managing grants and cooperative agreements; (9)

administers a national quarantine program to protect the U.S. against the introduction of diseases from foreign countries and the transmission of communicable disease between states; (10) facilitates appropriate cross-cutting collaboration with other NCs, CCID, other CDC programs, and external partners to promote effective surveillance for infectious threats to health; (11) designs and conducts epidemiologic studies to investigate the causes and risk factors for infectious diseases; (12) identifies, evaluates, and promotes the nationwide implementation of interventions designed to prevent infectious diseases, antimicrobial resistance, related adverse events, and medical errors among patients and healthcare personnel; (13) investigates and responds to outbreaks, emerging infections, and related adverse events among patients, healthcare providers, and others associated with the healthcare environment; (14) leads the improvement of domestic and international laboratory practices in clinical and public health laboratories through a quality systems approach; (15) provides services and expertise in development of quality systems to support compliance with FDA regulations on production, distribution, and use of laboratory diagnostic reagents; (16) provides support to CDC laboratories and investigators including provisions of animals, services, materials, and specialized expertise; and (17) provides emergency response coordination to CCID resources and enhanced epidemiologic, surveillance, and laboratory response capacity for bioterrorism and other infectious disease public health emergencies.

Office of the Director (CVK1). (1) Directs and manages the science, programs and activities of the NCPDCID; (2) provides leadership and coordination for the development and implementation of programs to enhance the prevention and control of infectious diseases nationally and internationally; (3) provides leadership and guidance on policy, program planning and development, program integration, management, and operations; (4) identifies and coordinates synergies between national centers and relevant partners; (5) provides technical information services to facilitate dissemination of relevant public health information; (6) provides liaison with other Governmental agencies and international organizations; (7) coordinates, in collaboration with the appropriate CCD and CDC components, international health activities relating to the prevention and control of infectious diseases; (8) advises the Director CCID and the Director, CDC, on policy matters concerning NCPDCID programs and activities; (9) coordinates development and review or regulatory documents and congressional reports; and (10) analyzes health programs and proposed legislation with respect to NCPDCID programs, goals and objectives.

Dated: April 10, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 07–1905 Filed 4–17–07; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0068]

Medical Device User Fee and Modernization Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss our proposed recommendations for the reauthorization of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA I) for fiscal years (FY) 2008 through 2012, as well as other proposals to improve the review of medical devices and the third party inspection program. These proposed recommendations were developed after discussions with the regulated industry. Section 105 of MDUFMA I directs FDA to publish these proposed recommendations in the **Federal Register**, hold a meeting at which the public may present its views on the recommendations, and provide for a period of 30 days for the public to provide written comments on the recommendations. The public meeting and comment period will provide an opportunity for public input on the proposed recommendations from all interested parties, including the regulated industry, scientific and academic experts, healthcare professionals, and representatives of patient and consumer advocacy groups.

DATES: The public meeting will be held on April 30, 2007, from 12 noon to 5 p.m. Registration to attend and to present at the meeting must be received by April 25, 2007. (See section III.B of this document for details on registration.) Submit written comments by May 18, 2007. Transcripts will be available approximately 30 days after the meeting. (See section III.C of this document for more details on transcript availability.)

ADDRESSES: The public meeting will be held at the Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information regarding this notice, contact*: Erik Mettler, Office of Policy and Planning, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *Erik.Mettler@fda.hhs.gov*.

For information regarding registration, contact: Cynthia Garris, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration (HFZ–220), 1350 Piccard Ave., Rockville, MD 20850, phone: 240–276–3150 ext. 121, FAX: 240–276–3151; e-mail: *cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

MDUFMA I (Public Law 107–250, October 26, 2002) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide FDA with the following new responsibilities and resources:

- User fees for premarket reviews of certain device premarket applications (see sections 737 and 738 of the act (21 U.S.C. 379i and 379j));
- Performance goals to improve medical device reviews (see section 101(3) of MDUFMA I and section 738(g)(1) of the act);
- Establishment inspections to be conducted by accredited third-parties when certain conditions are met (see section 704(g) of the act (21 U.S.C. 374)); and
- Improved oversight and coordination of reviews of combination products (products that combine devices, drugs, or biologics) (see section 503(g) of the act (21 U.S.C. 353(g))).

A. Medical Device User Fees and Performance Goals

In the years prior to MDUFMA I, FDA's resources for our device and radiological health programs had increased at a lower rate than FDA's

costs. As stated in the House Report to H.R. 3580:

The medical device industry is growing rapidly. The complexity of medical device technology is increasing at an equally rapid pace. Unfortunately, FDA's device review program lacks the resources to keep up with the rapidly growing industry and changing technology. Because prompt approval and clearance of safe and effective medical devices is critical to improving public health, it is the sense of the Committee that adequate funding for the program is essential. (U.S. Congress, House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002, report to accompany H.R. 3580, 107th Cong., 2nd sess., part 1 (Washington: GPO, 2002), pp. 23.)

Section 102 of the House Report recognized the importance of user fees in improving the device review program:

This title gives FDA the authority to collect user fees from manufacturers seeking to market medical devices. In this new program, manufacturers pay fees to FDA in exchange for FDA's agreement to endeavor to meet device review performance goals that will significantly improve the timeliness, quality, and predictability of the agency's review of devices. (Id. at 23–24.)

Under MDUFMA I, the industry provides funds through user fees that are available to FDA, in addition to appropriated funds, to spend on the device review process. Our authority to collect and spend user fees is ''triggered'' only in years when a base amount of appropriated funds, adjusted for inflation, is appropriated and spent on the process for the review of device applications.

In return for the additional resources provided by medical device user fees, FDA is expected to meet performance goals defined in a November 14, 2002, letter from the Secretary of the Department of Health and Human Services to the Chairman and Ranking Minority Members of the Committee on Health, Education, Labor and Pensions Committee of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. This letter is generally referred to as the ''FDA Commitment Letter.'' See 148 Cong. Rec. S11549–01 (2002). A few goals applied during FY 2003 and FY 2004, allowing FDA time to hire staff, build infrastructure, provide guidance to industry, and take other actions to implement the new law. More goals went into effect each year from FY 2005 through FY 2007, and the goals become more ambitious each year. These goals include ''FDA decision'' goals, under which FDA makes a specific decision within a specified time (and similar goals for FDA to ''review and act on'' certain biologics applications within a specified time), and cycle goals, which refer to FDA actions prior to a final action on a submission. These goals apply to the review of device premarket approvals (PMAs), panel-track supplements, premarket reports, expedited PMAs, 180-day PMA supplements, and 510(k)s in FDA's Center for Devices and Radiological Health (CDRH) and FDA's Center for Biologics Evaluation and Research (CBER), and to Biologics License Applications (BLAs), BLA supplements, and BLA resubmissions, and BLA supplement resubmissions in CBER. Phased in over the 5 years of MDUFMA I, the final goals for FY 2007 included an FDA decision on:

- 90 percent of PMAs, panel-track supplements, and premarket reports within 320 days;
- 50 percent of PMAs, panel-track supplements, and premarket reports within 180 days;
- 90 percent of expedited PMAs within 300 days;
- 90 percent of 180-day PMA supplements within 180 days;
- 80 percent of 510(k)s within 90 days;
- 90 percent of standard BLAs within 10 months;
- 90 percent of priority BLAs within 6 months;
- 90 percent of standard BLA efficacy supplements in 10 months;
- 90 percent of priority BLA efficacy supplements within 6 months;
- 90 percent of ''Class 1'' BLA resubmissions and BLA supplement resubmissions within 2 months;
- 90 percent of ''Class 2'' BLA resubmissions and BLA supplement resubmissions within 6 months; and
- 90 percent of BLA manufacturing supplements requiring prior approval within 4 months.

The goals also included interim cycle goals that were phased in over time. FDA is on track to meet or exceed nearly all of these performance goals. These performance goals, as outlined in the FDA Commitment Letter, will no longer be in effect after MDUFMA I sunsets on October 1, 2007. See section 107 of MDUFMA I.

B. Other Topics in MDUFMA I

In addition to its provisions relating to medical device user fees and performance goals, MDUFMA I contained other provisions. These provisions include:

- Authorization for a program that allows establishment inspections to be conducted by third party accredited persons (APs), under carefully prescribed conditions;
- Establishment of a new office in the Office of the Commissioner to coordinate the review of combination products;
- Authorization to require electronic registration of device establishments, once FDA finds that electronic registration is feasible; and
- Explicit authorization for the ''modular'' review of PMAs.

The user fees provided by MDUFMA I, and the additional appropriations anticipated by the new law, have allowed us to make improvements in the device review program. FDA's progress towards meeting MDUFMA I's performance goals has been accomplished through:

- Targeted hiring, including medical specialists, statisticians, software experts, and engineers;
- Increased use of outside experts, particularly for novel technologies;
- Improvements to FDA's information technology systems, such as enhanced tracking of applications and reporting systems; and
- Additional guidance documents that assist industry in preparing their applications to better address regulatory issues, such as how to qualify for small business fee waivers and discounts, how to prepare a ''modular'' premarket approval application, and how to obtain expedited review of a premarket submission.

These actions have led to improved FDA review times and greater predictability in the device review process.

In addition, we have made significant progress towards meeting other fundamental objectives of MDUFMA I. For example, FDA established an Office of Combination Products that is improving coordination of combination product reviews. Combination products are products comprised of different types of regulated articles (i.e., drug-device, drug-biologic, and device-biologic products). Although primary responsibility for the oversight of these products remains with the product Centers, the Office of Combination Products assigns combination products to the product Centers, ensures the timely and effective premarket review of combination products, and ensures the consistency and appropriateness of postmarket regulation of combination products. FDA also met the statutory requirement to establish a third-party inspection program. This option may be particularly useful to U.S. firms who

compete in international markets and are faced with multiple sets of regulatory requirements, as a single inspection may satisfy both U.S. and foreign requirements, and might also meet International Organization for Standardization (ISO) or other international standards requirements.

In August 2005, Congress passed the Medical Device User Fee Stabilization Act (Public Law 109–43, August 1, 2005) (MDUFSA), which modified several provisions of MDUFMA I.

MDUFSA:

- Repealed the FY 2003 and FY 2004 appropriations trigger requirements;
- Modified the FY 2005 through FY 2007 minimum appropriation requirements for the device and radiological health line of FDA's appropriation to be within 1 percent below the calculated appropriations trigger;
- Fixed annual fees for FY 2006 and FY 2007 at an amount providing an 8.5 percent rate of increase each year;
- Expanded the definition of ''small business'' for FY 2006 and FY 2007, making more firms eligible for reduced small business fees; and
- Repealed the ''compensating adjustment'' that allowed FDA to adjust user fee rates to make up for revenue lost when user fee revenues did not meet projections in a prior year.

The user fee provisions of MDUFMA I will sunset on October 1, 2007 if not reauthorized. In preparing our proposed recommendations for reauthorization, we have conducted technical discussions with the regulated industry and have consulted with stakeholders each year at a public meeting as required by law.

Congress directed FDA to publish in the **Federal Register** the proposed recommendations developed through this process after negotiations with the regulated industry, present the proposed recommendations to the congressional committees specified in the statute, hold a public meeting at which the public can present its views on the proposed recommendations, and provide for a period of 30 days for the public to provide written comments on the proposed recommendations. See section 109 of MDUFMA I.

The purpose of this notice is to publish the recommendations we propose to offer Congress and announce the dates for the upcoming public meeting and written comment period. After the public meeting and the close of the 30-day comment period, we will undertake a careful review of all the public comments we receive on these proposed recommendations.

II. What We Are Proposing to Recommend to Congress?

Our goal for the legislative package to reauthorize medical device user fees and to make other improvements (MDUFMA II) is to build upon the performance goals we are pursuing for FY 2007 while providing predictable user fees for industry and financial stability and predictability in funding for FDA over the next 5 years. Our proposed recommendations fall into the following two major categories: (1) Proposals to ensure sound financial footing for the medical device review program and (2) proposals to enhance the process for premarket review of device applications.

A. Proposed Recommendations to Ensure Sound Financial Footing

Although user fees have provided substantial resources to FDA since the beginning of the program, total resources for medical device review, including funds from both appropriations and user fees, have not kept up with our increasing costs. FDA has experienced an increase in our costs of pay and benefits per ''full time equivalent'' (FTE) averaging 5.8 percent per year over the most recent 5 years. Nonsalary costs, including the costs of rent and contract support, have also increased at the same rate per FTE. We are proposing changes to the financial provisions of MDUFMA I to place FDA on more sound financial footing so we can continue with the program and make enhancements to it.

1. Adjustment of Total Revenue for Device Review to Ensure a 6.4 Percent Increase From Year to Year Over the Next 5 Years

Detailed analysis of FDA's recent costs history and anticipated increased costs over the next 5 years anticipate annual increases at 6.4 percent each year. Increases of 6.4 percent per year are necessary for FDA to be able to maintain the current level of staff to support the medical device review process. The primary drivers of this rate of increase are rent, security, and statutorily mandated payroll and benefits increases. In developing cost estimates for MDUFMA II, we used our FY 2005 spending on the device review process (including fees and appropriations) and estimated that the costs for the program would increase at 6.4 percent each year. Table 1 of this document represents FDA's estimate of the total resources it will need for device review from appropriations and user fees combined over the 5-year period 2008 through 2012.

TABLE 1.—TOTAL RESOURCES NEEDED FOR THE DEVICE REVIEW PROCESS ($ MILLIONS)

Fiscal Year	2008	2009	2010	2011	2012	5-Year Total
Dollars (millions)	$220	$234	$249	$265	$281	$1,249

The annual fee increases assumed will ensure a stable program that will not increase over the 5 years of MDUFMA II, but that should remain stable in its capabilities and personnel strength. The proposed fee structure would have application fees lower than those paid in 2007 in almost all application categories over the 5 years of MDUFMA II, but would add new annual establishment and annual report fees and some new application fees (discussed more below). Total fee revenues in FY 2008 would increase by approximately 31 percent over estimated FY 2007 fee revenues, and by 8.5 percent per year each subsequent year through FY 2012, as shown in table 2 below.

TABLE 2.—TOTAL ESTIMATED FEE REVENUES ($ MILLIONS)

Fiscal Year	2008	2009	2010	2011	2012	5-Year Total
Total	$48.5	$52.5	$57.0	$61.9	$67.1	$287.0

2. More Stable Fee Structure

All fee revenues in MDUFMA I were derived from application fees only, which fluctuated significantly from year to year. Under MDUFMA I, fee revenues repeatedly fell short of expectations. FDA is proposing to recommend two new fees in MDUFMA II that would generate about 50 percent of the total fee revenue and that would be more stable than application fees. The new fees are: (1) An annual establishment registration fee and (2) an annual fee for filing periodic reports. This would allow for significant reduction in MDUFMA II of existing application fees.

The establishment fee would be paid once each year by each device manufacturer (including an establishment that sterilizes or otherwise makes a device for a specification developer or any other person), single-use reprocessor, and specification developer. It is proposed to start at $1,706 in 2008 and would generate about $21.8 million (45 percent of total fee revenues), assuming that 12,750 establishments pay this fee. (The proposal would allow an increase in FY 2010 over the annual rate of increase if fewer than 12,250 establishments pay the fee in FY 2009 to ensure that the fees collected from this source total 45 percent of fee revenues. This increase would not be more than 8.5 percent above the annual rate of increase.) A firm would not be considered to be legally registered each year without the payment of this fee, which is to be completed electronically.

The annual fee for filing periodic reports is proposed to start at $6,475 in FY 2008 and would generate about $2.5 million in FY 2008, or about 5 percent of fee revenues assuming that we receive reports on 425 devices subject to periodic reporting and 10 percent pay the reduced small business fee of $ 1,619.

The remaining 50 percent of revenues would come from application fees. All proposed application fees would be significantly lower than they were in FY 2007. The proposed fee for a PMA or BLA would be set at $185,000 in FY 2008—34 percent less than the $281,600 charged in FY 2007. The proposed fee for a panel-track supplement would be charged at 75 percent of the rate for a PMA, rather than at 100 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed panel-track supplement fee in FY 2008 of $138,750 would be 51 percent less than the FY 2007 fee of $281,600. The fee for a 180-day PMA supplement is proposed at 15 percent of the PMA fee, rather than at 21.5 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed 180-day PMA supplement fee in FY 2008 of $27,750 would be 54 percent less than the FY 2007 fee of $60,544. The fee for a real-time supplement is proposed at 7 percent of the PMA fee, rather than at 7.2 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed real-time supplement fee in FY 2008 of $12,950 would be 36 percent less than the FY 2007 fee of $20,275. The fee for a 510(k) is proposed at 1.84 percent of the PMA fee, rather than at 1.42 percent of that rate as was the case in FY 2003 through FY 2007, so the proposed 510(k) fee in FY 2008 of $3,404 would be 18 percent less than the FY 2007 fee of $4,158.

FDA is proposing two new fees for applications not currently subject to fees. They are: (1) A fee for 30-day notices (making modifications to manufacturing procedures or methods) that would be 1.6 percent of the fee for a full PMA (for a 30-day notice fee of $2,960 in FY 2008) and (2) a fee for a request for classification information under section 513(g) that would be assessed at 1.35 percent of the cost of a full PMA (for a 513(g) fee of $2,498 in FY 2008). Both of these applications require significant work by FDA, and the proposed fees reflect the work that they involve, on average.

Each of the proposed fees would increase each year by 8.5 percent to ensure that fee revenues contribute their expected share to total program costs, and to provide industry with stability and predictability in the fee revenues it would expect to pay.

3. Changes in the Fee Structure for Small Businesses

In an effort to reduce the burden on small businesses, FDA is proposing to reduce the rates paid by firms meeting the definition of a small business under MDUFMA. The criteria for meeting the small business definition is not proposed to change, other than as discussed below for entities that do not file returns with the U.S. Internal Revenue Service, but the proposed fee rates for qualifying small businesses would be lower. We are proposing to reduce the rates for small businesses for premarket applications, panel-track PMA applications, BLA efficacy supplements, 180-day PMA supplements, real-time PMA supplements, and annual reports, from 38 percent to 25 percent of the standard fee for the particular type of submission. We are also proposing to reduce the rates for small businesses for 30-day notices, 510(k) premarket notification submissions, and 513(g) requests for classification information from 80 percent to 50 percent of the standard fee for the particular type of submission. These are significant reductions that should provide substantial relief to qualifying small businesses.

The following table summarizes the reductions in fees for qualifying small businesses proposed for FY 2008.

TABLE 3.—MEDICAL DEVICE USER FEES PROPOSED FOR FY 2008

Type of Fee	Standard Fee	Small Business Fee
Premarket application (PMA, BLA, premarket report, product development protocol)	$185,000	$46,250
Panel-track PMA supplement	$138,750	$34,688
180-day PMA supplement	$27,750	$6,938
BLA efficacy supplement	$185,000	$46,250
Real-time PMA supplement	$12,950	$3,237
30-day notice	$2,960	$1,480
510(k) premarket notification submission	$3,404	$1,702
Request for classification information	$2,498	$1,249

In addition, FDA is proposing that the small business provisions be expanded to allow a way for firms that do not file tax returns with the U. S. Internal Revenue Service to also qualify for small business rates, based on certifications from the national taxing authorities where the firm and each of its affiliates file their taxes, and signed affidavits from the head of the firm or its chief financial officer and from each of its affiliates.

4. Technical Changes to Increase Administrative Efficiency of the User Fee Program

We are proposing a change to the current offset provision of MDUFMA I. The current provision requires us to reduce fees in a subsequent year if collections in any year exceed the amount appropriated, but does not have a parallel provision to increase fees in a subsequent year if collections fall short of amounts appropriated from fees. The modification we are recommending to propose would allow us to aggregate all fees collected over the first four years of MDUFMA II, from FY2008 through FY 2011 and compare that amount to the aggregate amount appropriated for the same period. A reduction would be made in fees in the final year only if the amount collected in the 4-year period exceeds the amount appropriated for the same period. We believe this aggregation over 4 years provides for greater financial stability for FDA than treating each year in isolation.

5. Electronic Registration

FDA is proposing to change section 510(p) of the act (21 U.S.C. 360(p)) to facilitate the submission of registration and listing information by electronic means, except in those rare situations where FDA agrees that electronic submission is not feasible, in order to collect establishment registration fees for FY 2008. The modification would require electronic submission of registration and listing information without going through the rulemaking process to ensure timely collection of establishment registration fees for FY 2008. We believe electronic registration is essential for efficient implementation of any proposal for an establishment registration fee.

6. Triggers

MDUFMA I has three triggers. One tied to appropriations for the device line and two tied to agency spending on device review and inspections. We are proposing to extend the current triggers through MDUFMA II.

B. Enhancing the Process for Premarket Review

In the area of premarket review, FDA is proposing to recommend enhancements in the following eight areas: (1) Performance goals; (2) interactive review; (3) guidance document development; (4) diagnostic imaging products; (5) in vitro diagnostics; (6) meetings; (7) quarterly performance reports; and (8) reviewer training.

1. Performance Goals

FDA is proposing to meet more rigorous goals for MDUFMA II that build on the progress made in MDUFMA I. In making these proposals, we have taken into account the efficiencies accomplished in MDUFMA I and planned for in MDUFMA II. These efficiencies include additional scientific, regulatory, and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and information technology improvements that allow us to better track and manage the device review process.

In MDUFMA II, we are proposing to eliminate the cycle goals that we believe are an impediment to reaching the ultimate objective of MDUFMA—to get safe and effective devices to patients and healthcare professionals more quickly. In order to meet the performance goals in the FDA Commitment Letter, we put business processes in place to meet the goals for final decisions, as well as for interim cycle goals. However, FDA believes that an unintended consequence of the cycle goals is that, because we must determine whether or not to send a major deficiency letter, ''not approvable'' letter, or other interim action earlier in the review process, we are less likely to have sufficient time to engage in informal interactions with the applicant to resolve outstanding questions before making that determination. Consequently, we are more likely to issue a negative interim decision. We are proposing to eliminate these cycle goals and only have performance goals for final decisions.

In MDUFMA II, we are proposing to improve our performance in reaching a final decision for the following applications:

- A decision for 60 percent of nonexpedited PMAs and panel-track PMA supplements within 180 days and for 90 percent within 295 days;
- A decision for 50 percent of expedited PMAs and expedited panel-track PMA supplements within 180 days and for 90 percent within 280 days;
- A decision for 90 percent of 510(k)s within 90 days and for 98 percent within 150 days;
- A decision for 85 percent of 180-day PMA supplements within 180 days and for 95 percent within 210 days;[1] and
- A decision for 80 percent of real-time PMA supplements within 60 days and for 90 percent within 90 days.

We are also adding a goal for PMA modules in MDUFMA II. We are proposing to take action on 75 percent of PMA modules within 90 days, and for 90 percent within 120 days.

Where specific quantitative goals have not been established, we are proposing that we would, at a minimum, maintain current performance in review areas, such as for investigational device exemptions (IDEs) and 30-day notices.

2. Interactive Review

Under the proposed recommendations, we would continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and sponsors to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and sponsors. Interactive review is intended to: (a) Prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process; (c) minimize the number of review cycles and the extent of review questions conveyed through formal requests for additional information; and (d) ensure timely responses from sponsors. We believe that all forms of communication should be used as tools to facilitate interactive review, including, but not limited to, the following: (a) E-mail; (b) one-on-one telephone calls; (c) telephone conferences; (d) videoconferencing; (e) fax; and (f) face-to-face meetings.

3. Guidance Document Development

Under the proposed recommendations, we would continue to develop guidance documents to the extent possible without adversely impacting the review timeliness for MDUFMA-related submissions. In addition, FDA would post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

[1] Under MDUFMA I, FDA issues a ''not approvable'' letter to indicate deficiencies in an application and to request additional information, which counts as an action that meets the goals for 180-day PMA supplements. Under MDUFMA II, the reviewer in the same situation will be able to issue a ''major deficiency'' letter, which will not count towards meeting the 180-day PMA supplement goals. The MDUFMA II goal will be more ambitious in practice because it reflects a more meaningful decision, reached after FDA has worked with the sponsor to discuss deficiencies and to obtain additional information.

4. Diagnostic Imaging Products

Diagnostic imaging devices that are sometimes used concurrently with diagnostic drug and biological products (such as contrast agents and radiopharmaceuticals)—so-called ''concomitant use products''—present important questions of efficient regulation and consultation between product Centers that are similar to those raised by combination products.

In response to these concerns, FDA would develop a guidance document, after consultation with affected parties, intended to ensure timely and effective review of, and consistent and appropriate postmarket regulation and product labeling requirements for, diagnostic imaging devices used with approved imaging contrast agents and/or radiopharmaceuticals. We propose to publish draft guidance by the end of FY 2008 and allow for a 90-day public comment period. We propose to issue a final guidance within one year of the close of the comment period.

5. In Vitro Diagnostics (IVDs)

To facilitate the development of IVD devices, FDA would continue to explore ways to clarify regulatory requirements and to reduce regulatory burden, as appropriate. FDA proposes to:

- Draft or revise guidance on the conduct of clinical trials involving de-identified leftover specimens, clinical trial design issues for molecular diagnostic tests, migration studies, herpes simplex virus, enterovirus, and influenza testing;
- Conduct a pilot program to evaluate integrating the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA) waiver review processes for possible increased efficiencies. This pilot would include only voluntary participants from industry, and the applications involved in the pilot would not be counted toward the MDUFMA II performance goals.
- Consider industry proposals on acceptable CLIA waiver study protocols, develop acceptable protocol designs, and make them available by adding appendices to the guidance or by posting redacted protocols on the OIVD Web site.
- Track and report our performance on CLIA waiver applications and share this information with industry annually and then evaluate, at the end of year two, whether user fees and performance goals for CLIA waivers should be considered for MDUFMA III;
- Review a list of class I and II low risk IVD devices, provided by industry, to determine whether any of them could be exempted from premarket notification and allow interested parties to petition for exemptions consistent with 510(m)(2);
- Conduct a review of the pre-IDE program to address issues raised by industry.

6. Meetings

FDA would make every effort to schedule informal and formal meetings, both before and during the review process, in a timely way, and industry would make every effort to provide timely and relevant information to make the meetings as productive as possible. These meetings include, but are not limited to the following: pre-submission meetings, determination meetings, agreement meetings, and 100-day meetings.

7. Quarterly Performance Reports

FDA would report quarterly its progress toward meeting the quantitative goals described in this letter. In addition, for all submission types, we would track total time (time with FDA plus time with the company) from receipt or filing to final decision (approval, denial, substantial equivalence (SE), or nonsubstantial equivalence (NSE)). We would also provide, on an annual basis, de-identified review performance data for the branch with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements.

8. Reviewer Training

As resources permit, FDA would apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. We would provide summary information on the types of training provided to staff on an annual basis.

C. Third Party Inspection Program

FDA is proposing to recommend changes to the third party accredited person (AP) inspection program in three major areas. APs are firms trained and accredited by FDA to conduct biennial inspections of certain medical device firms for compliance with good manufacturing practices. The proposals are intended to increase the quantity of useful information FDA has about the compliance status of medical devices marketed in the United States and to permit FDA to focus its inspectional resources on those firms and products posing the greatest risk to public health.

First, FDA is proposing to streamline the administrative burdens associated with qualifying for the program. For example, rather than having to petition FDA for clearance to use an AP, the proposal would require only that firms provide FDA with 30 days prior notice of their intent to use an AP listed on FDA's Web site.

Second, we are proposing to expand participation in the program. For example, the current AP program restricts qualified manufacturers of class II and class III medical devices to two consecutive AP inspections after which FDA must conduct the next inspection, unless the manufacturer petitions and receives a waiver from us. We are proposing to permit firms to use APs for an unlimited number of consecutive inspections without seeking a waiver. However, we would continue to conduct ''for cause'' or follow-up inspections whenever we deem such inspections appropriate.

Third, we are proposing to permit device companies to voluntarily submit to FDA reports by third parties assessing conformance with an appropriate international quality systems standard, such as those set by the International Standards Organization. We would consider the information in these reports in setting our inspectional priorities.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will We Use?

Through this notice, we are announcing the convening of a public meeting to hear stakeholder views on the recommendations we propose to provide to Congress on the reauthorization of MDUFMA II.

We will conduct the meeting on April 30, 2007. (see **ADDRESSES**). In general, the meeting format will include brief presentations by FDA, but will focus on hearing from different stakeholder interest groups (such as patient advocates, consumer advocates, industry, health professionals, and academic researchers). We will also give individuals the opportunity to make presentations at the meeting, and for organizations and individuals to submit written comments to the docket after the meeting.

B. How Do You Register for the Meeting or Submit Comments?

If you wish to attend and/or make a presentation at the meeting, send an e-mail message to Erik Mettler or Cynthia Garris (see **FOR FURTHER INFORMATION CONTACT**) by April 25, 2007. Your e-mail should include the following information: Name, company, company

address, company phone number, and e-mail address. You will receive a confirmation within 2 business days.

We also will accept walk-in registration at the meeting site, but space is limited, and we will close registration when maximum seating capacity (approximately 100) is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

Additionally, regardless of whether you wish to make a presentation or simply attend the meeting, please notify us if you need any special accommodations (such as wheelchair access or a sign language interpreter).

If you would like to submit comments regarding these proposed recommendations, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified 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. Submit your comments no later than May 18, 2007.

C. Will Meeting Transcripts Be Available?

We will prepare a meeting transcript and make it available on our Web site (*http://www.fda.gov*) after the meeting. We anticipate that transcripts will be available approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, between 9 a.m. and 4 p.m. Monday through Friday.

Dated: April 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–1919 Filed 4–16–07; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–4301]

Memorandum of Understanding Between the National Cancer Institute and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS). The purpose of this MOU is to establish a formal collaboration between FDA and NCI regarding the creation of a common standards-based data repository to facilitate the electronic exchange and analysis of data from research studies on investigational drugs in a fully secure manner.

DATES: The agreement became effective March 2, 2007.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation Research (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7784 e-mail: *randy.levin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: April 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-07-4301

MEMORANDUM OF UNDERSTANDING

between the

NATIONAL CANCER INSTITUTE

and the

FOOD AND DRUG ADMINISTRATION

on

Janus Study Data Repository

I. Purpose

The purpose of this memorandum of understanding (MOU) is to establish a formal collaboration between the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute (NCI) to create a common standards-based data repository to facilitate the exchange and analysis of study data.

This MOU sets forth an agreement between FDA and NCI regarding roles, responsibilities, financial commitments, and information-sharing for the development and implementation of the Janus study data repository and integrated analysis tools environment. The ultimate goal for the Janus project is to provide an environment that will enable NCI, FDA, and entities sponsoring research studies of investigational drugs (*Sponsors of Drugs and Biologics* or *Sponsors*) to exchange and manage study data electronically in a fully secure manner.

Janus is one of several modules under development as part of an NCI effort in its Center for Bioinformatics (NCICB) to facilitate the exchange of clinical research information between sponsors, including NCI, and FDA. To accomplish this objective, NCICB will make use of the cancer Biomedical Informatics Grid (caBIG™), which is a common infrastructure for sharing data, tools, and other resources among all entities engaged in cancer research. Janus will adhere to the caBIG™ principles of open source, open access, open development and federation and will be compatible with caBIG™ technical standards. Upon the successful implementation of Janus, FDA intends to encourage Sponsors of both investigational and marketing applications to use the system to submit their study data to FDA using standards developed by the Clinical Data Interchange Standards Consortium (CDISC). For the purposes of this MOU, *study data* refers to data and information required to be submitted to FDA, including clinical and preclinical data in support of an investigational or marketing application.

II. Background

The FDA/NCI Interagency Oncology Task Force (IOTF) was established in 2003 to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications and diagnostics. The FDA and NCI both have interests in expediting the development of new drugs. One of the central goals of the IOTF is to implement an electronic drug application submission system that will help reduce the delays, errors, and costs associated with drug development. Such a system is expected to speed the discovery and delivery of new therapies.

Janus, a primary component of such a system, is envisioned as a common electronic infrastructure that will help accelerate and streamline interactions between sponsors (including NCI) and FDA by facilitating the exchange of CDISC-compatible study data. Once implemented, Janus is intended to enable sponsors (including NCI) and FDA to exchange and manage study data electronically in a fully secure manner. This MOU relates solely to Janus. NCI and FDA will work together to develop subsequent MOUs (or addenda to this MOU) related to other modules of an electronic product information exchange system.

III. Substance of Agreement; Responsibilities of NCI and FDA

This MOU addresses activities related to the development and implementation of Janus. Information in the Janus study data repository will fall into two categories, which, for the purposes of this MOU are referred to as *FDA records* and *non-FDA records*. *FDA records* refers to any information entered into the Janus repository by or on behalf of FDA, as well as any information, regardless of who enters it into Janus, once it is electronically submitted to FDA. For information entered into Janus by a sponsor (including NCI) to become an *FDA record*, the system will require the submitter to take an affirmative step acknowledging the fact that the data are now accessible by the FDA. This will be considered a submission to FDA. Once so submitted to FDA, the information becomes available to the FDA and becomes an FDA record. *Non-FDA records* are any information not entered into Janus by or on behalf of FDA, as well as information entered into Janus by a sponsor prior to taking the affirmative step that constitutes submission to FDA.

FDA and NCI will establish a Change Management Board, comprising representatives of both agencies, to discuss Janus's technical requirements and to discuss and decide on changes or enhancements to the technical capabilities of Janus.

Development of Janus will occur in four phases: (1) development and testing, (2) operational pilot testing, (3) production deployment, and (4) actual production. During phases 1, 2, and 3 of the project, FDA will transfer certain existing FDA information related to CDISC-compatible study data to NCI for the sole purpose of preparing such records for entry into the Janus repository. To get Janus established, during phases 1, 2, and 3, both FDA and NCI will have access to these FDA records and NCI's access to FDA records during this period is subject to the restrictions enumerated in III.A. of this agreement. After the conclusion of phase 3, NCI will not seek to access records in the FDA records component of Janus. During the first 6 months of phase 4, the system will limit access to FDA records solely to FDA and the contractor functioning as NCI's

database administrator for Janus, and the contractor will be bound by the same restrictions set forth in III.A. of this agreement. Thereafter, only FDA will have access to FDA records. Information entered into Janus by or on behalf of FDA will reside only in the FDA records component. Notwithstanding all of the foregoing, however, it is understood that NCI may be required to access records on its server if so required by law.

The specific responsibilities of the two parties to this MOU are as follows:

A. The National Cancer Institute (NCI)

- NCI will lead the development of Janus and provide for the maintenance of all hardware, software, and databases.
- NCI will design Janus to meet the requirements identified for the implementation of Janus. Changes or enhancements to the technical capabilities of Janus will only be made upon the approval of the Change Management Board.
- NCI will ensure that the data collected, stored, and exchanged through Janus meet applicable FDA requirements set forth in 21 CFR Part 11.
- NCI will not seek to access to any FDA record once the record has been submitted to FDA during phase 4, except as already permitted in accordance with any applicable FDA Privacy Act System Notice or the FDA disclosure regulations set forth in 21 CFR Part 20 or as otherwise required by law. However, the system may be designed to permit sponsors, including NCI, to create a mirror or duplicate of the record in the non-FDA records component of Janus. NCI will protect all FDA records from disclosure in accordance with applicable laws and regulations.
- For information transferred by FDA to NCI for preparation and entry into Janus during phases 1, 2 and 3, NCI agrees that, except as necessary for facilitating the information's entry into Janus, NCI will not use or disclose such information outside the Department of Health and Human Services without FDA's express written permission, except to the extent required by law. Furthermore, before giving its contractor access to any information transferred by FDA to NCI for preparation and entry into Janus, NCI will procure written agreement from its contractor not to further use or disclose such information, except to the extent required by law.
- If for any reason NCI plans to discontinue the maintenance of Janus, NCI will give FDA 60 days' advanced notice of this decision and transfer the system, software, and FDA records, as well as documentation, procedures and instructions concerning the normal and emergency operation of the Janus software, to FDA, or another party mutually agreed upon and in compliance with all applicable laws and regulations, in a timely fashion.

B. The Food and Drug Administration (FDA)

- FDA will inform NCI of all necessary server security requirements.
- FDA will work with NCI to ensure that Janus contains all necessary server security requirements.

- FDA will develop a transition plan to migrate FDA's current CDISC-compliant study data to the Janus repository, which is intended to eventually become FDA's repository for storing and obtaining access to study data required under 21 CFR 312.
- FDA staff will enter into the FDA records portion of Janus relevant CDISC-compatible study data submitted to FDA as part of new product applications as well as other data generated by FDA (e.g., metadata for the product applications associated with the CDISC-compatible study data).

IV. Funds

None of the activities outlined above currently requires the exchange of funds between NCI and FDA. In the event that the transfer of funds is deemed to be required in the future, the parties may enter into an interagency agreement pursuant to Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535).

V. Information-Sharing, Reports, and Notices

FDA shall determine, in compliance with applicable law, whether to disclose information in the FDA records component of Janus. Proprietary and/or nonpublic information submitted by sponsors, including NCI, to the Non FDA records component of Janus will not be publicly disclosed by NCI, unless such disclosure is governed by appropriate confidentially disclosure agreements, or to the extent such disclosure is required by law. If NCI receives a request, order, or demand for FDA records, including a request under the Freedom of Information Act, 5 U.S.C. 552, NCI will refer that request to FDA for response.

VI. Liaison Officers

Randy Levin
Director for Bioinformatics
Food and Drug Administration
Tel: 301-827-7784

NCI Project Officer
Peter Covitz
Chief Operating Officer
Center for Bioinformatics
National Cancer Institute
Tel: 301-402-0326

VII. Duration of MOU; Modifications; Termination

This MOU shall become effective on the date of signature by the parties and shall remain in effect for two (2) years unless modified by the mutual agreement of the parties upon sixty (60) days'

notice in writing, or until such time as the system and software have been transferred to the FDA or a mutually agreed upon third party. If either party wishes to terminate this MOU, it may do so by giving 60 days' advance notice of this decision to the other party and must ensure that records belonging to the other party are transferred to the other party in a timely fashion.

VIII. SIGNATURES OF RESPONSIBLE PARTIES

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

Date 1/27/07

Janet Woodcock, M.D.
Deputy Commissioner and Chief Medical Officer
U.S. Food and Drug Administration

APPROVED AND ACCEPTED FOR THE NATIONAL CANCER INSTITUTE

Date 3-2-07

John E. Niederhuber, M.D.
Director
National Cancer Institute

[FR Doc. 07–1921 Filed 4–17–07; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Smallpox Vaccine Injury Compensation Program (OMB No. 0915–0282)—Extension

The Smallpox Emergency Personnel Protection Act (SEPPA) authorized the Secretary of Health and Human Services to establish the Smallpox Vaccine Injury Compensation Program, which provides benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures.

The benefits available under the Program include compensation for unreimbursed medical care and lost employment income, and survivor death benefits. To be considered for Program benefits, requesters (i.e., smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on their behalf as their representatives, must file a Request Form and the documentation required to show that they are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, a vaccinia contact, a survivor, or a representative of an estate.

All requesters must submit medical records sufficient to demonstrate that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total Burden hours
Request Form	25	1	25	5	125
Certification	25	1	25	1	25
Total	25	.....	25	.....	150

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 11, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–7304 Filed 4–17–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995, and as last amended September 21, 2004; 69 FR 56433–56445).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice establishes the Bureau of Clinician Recruitment and Service (RU) and moves the National Health Service Corps, the Nursing Scholarship Program, the Nursing Education Loan Repayment Program, the Faculty Loan Repayment Program, and the Native Hawaiian Scholarship Program from the Bureau of Health Professions (RP) to this newly established Bureau.

Chapter RU, Bureau of Clinician Recruitment and Service

Section RU, 00 Mission

The mission of the Bureau of Clinician Recruitment and Service is to improve the health of the Nation's underserved communities and vulnerable populations by coordinating the recruitment and retention of caring health professionals in the healthcare system and supporting communities' efforts to build more integrated and sustainable systems of care.

Section RU, 10 Organization

The Bureau of Clinician Recruitment and Service (BCRS) is headed by the Associate Administrator who reports directly to the Administrator, Health Resources and Services Administration. The BCRS includes the following components:

(1) Office of the Associate Administrator (RU);

(2) Legal & Compliance Office (RU1);

(3) Division of Site and Clinician Recruitment (RU2);

(4) Division of Applications and Awards (RU3); and

(5) Division of Scholar and Clinician Support (RU4).

Section RU–20, Functions

Office of the Associate Administrator (RU)

Provides overall leadership, direction, coordination, and planning in support of Bureau programs: The NHSC Scholarship Program, NHSC Loan Repayment Program, the Native

Hawaiian Health Scholarship Program, the Nursing Scholarship Program, the Faculty Loan Repayment Program, and the Nursing Education Loan Repayment Program: (1) Establishes program goals, objectives and priorities, and provides oversight as to their execution; (2) plans, directs, coordinates and evaluates Bureau-wide management activities; (3) maintains effective relationships within HRSA and with other HHS organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with improving the health status of the Nation's underserved communities and vulnerable populations by recruiting and retaining health care clinicians into service in areas of greatest need; (4) plans, directs and coordinates Bureau-wide administrative management activities, i.e., budget, personnel, procurements, delegations of authority, and has responsibilities related to the awarding of BCRS grant funds; and (5) oversees the development of BCRS program policies.

Legal and Compliance Office (RU1)

(1) Analyzes, administers and manages procedures to perform responsibilities for the NHSC Scholarship Program, NHSC Loan Repayment Program (LRP), Native Hawaiian Health Scholarship Program, Nursing Scholarship Program, the Faculty Loan Repayment Program, and Nursing Education Loan Repayment Program for scholarship and loan repayment participants who have breached their service obligation, requested a waiver or suspension of their service obligation, or who are in default and have agreed to serve under a Forbearance Agreement, as a result of judgments, or signed Special Repayment Program Agreements; (2) reviews default recommendations; determines the action of default (breach of contract); notifies appropriate financial organization that a scholar or LRP participant has been placed in default, the reason for default, the date of default and the days of credit, if any, towards service obligation; and takes other appropriate actions; (3) provides programmatic information to Agency officials, the Office of the General Counsel, the Office of Inspector General, Division of Fiscal Services, and the Assistant United States Attorneys at the Department of Justice for trials, bankruptcy hearings, and other activities; (4) serves as a point of contact for responding to inquiries, disseminating information and providing technical assistance concerning defaults, waivers, suspensions and default payment obligations; and (5) develops and implements policies and procedures in conjunction with default reduction activities and other actions to maximize compliance with scholarship and loan repayment service obligations.

Division of Site and Clinician Recruitment (RU2)

Works with sites located in Health Professional Shortage Areas (HPSA) to support recruitment, retention and effectiveness of BCRS clinicians. Specifically: (1) Conducts student, clinician and site recruitment and outreach activities; (2) provides oversight, processing and coordination of reviews of all BCRS site applications including the Ambassadors Program, J1–Visas, Ready Responders, Native Hawaiian Health Scholarship Program and demonstration projects; (3) maintains all vacancy management activities; (4) facilitates scholar placement; (5) conducts site application review; and (6) is responsible for all communication functions including but not limited to the Web site, HRSA Call Center and newsletters; and coordinates all Bureau conferences.

Division of Applications and Awards (RU3)

The Division of Applications and Awards processes applications and makes awards for the NHSC Scholarship Program, the NHSC Loan Repayment Program, Nursing Education Loan Repayment Program, Nursing Scholarship Program, and the Faculty Loan Repayment Program. Specifically: (1) Reviews, ranks and selects participants for the scholarship and loan repayment programs; (2) serves as the point of contact for responding to inquiries, disseminating program information, and providing technical assistance pertaining to scholarship and loan repayment applications and awards; (3) awards scholarships and loan repayment contracts to individuals selected; (4) verifies and processes loan and lender related payments in prescribed manner; and (5) maintains current information on scholarship and loan repayment applications and awards through automated BCRS information systems.

Division of Scholar and Clinician Support (RU4)

The Division of Scholar and Clinician Support initiates contact with and supports scholars entering the site selection phase and provides ongoing support to all clinicians with a formal affiliation with the BCRS. Assures contact with BCRS clinicians throughout their period of obligated service. Specifically: (1) Monitors, counsels, approves deferments, recommends suspensions and if necessary recommends defaults of all program participants; (2) monitors service and sites, coordinates technical assistance, processes transfer requests, reassignments, suspensions, and default recommendations, closes individual personnel files, issues completion certificates, and completes annual retention reports.

Section RU–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effective pending further re-delegation.

This reorganization is effective upon the date of signature.

Dated: April 11, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–7306 Filed 4–17–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; 67 FR 46519, July 15, 2002; and 68 FR 787–793, January 7, 2003; 68 FR 64357–64357, November 13, 2003; 68 FR 64357–64357–64358, 70 FR 42347–42348, July 22, 2005; 71 FR 69135–69137, as last amended November 29, 2006).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice establishes the Office of Financial Management (RB) and changes the organizational title of the Office of Administration and Financial Management (RS) to the Office of Management (RS). This notice also transfers the Division of Financial Management (RS2) from the Office of Administration and Financial Management (RS) to the newly established Office of Financial Management (RB).

Chapter RB—Office of Financial Management

Section RB–00, Mission

To provide staff financial advisory services to the Administrator, management staff and operating units of the Health Resources and Services Administration (HRSA).

Section RB–10, Organization

The Office of Financial Management (OFM) is headed by the Chief Financial Officer who reports directly to the Administrator, Health Resources and Services Administration. The OFM includes the following components:

(1) Office of the Chief Financial Officer (RB);

(2) Division of Budget (RB1); and

(3) Division of Financial Policy and Controls (RB2).

Section RB–20, Functions

Office of the Chief Financial Officer (RB)

(1) Provides leadership and coordination in the development and administration of the Health Resources and Services Administration's (HRSA) financial management policies; (2) develops budget submissions for HRSA; (3) collaborates with the HRSA Office of the Administrator (OA) in the development and implementation of long-range program and financing plans; (4) participates in budget reviews and hearings; (5) manages HRSA's system of internal budgetary planning and control of funds; (6) develops and implements HRSA-wide budgetary, financial systems and procedures; (7) conducts HRSA-wide FTE tracking; (8) prepares all applicable financial reports; (9) analyzes data and makes recommendations to assure effective safeguards are in place to prevent fraud, waste and abuse; (10) identifies or conducts special financial management training programs for OCFO and HRSA staff components; and (11) maintains liaison with the Department of Health and Human Services (DHHS), Office of Management and Budget, Congress, and other Government organizations on financial management matters.

Division of Budget (RB1)

(1) Reviews funds control measures to assure that no program, project or activity of HRSA obligates or disburses funds in excess of appropriations or obligates funds in violation of authorized purposes; (2) provides advice and assistance to senior HRSA management to verify the accuracy, validity, and technical treatment of budgetary data in forms, schedules, and reports, or the legality and propriety of using funds for specific purposes; (3) maintains primary liaison to expedite the flow of financial management work and materials within the Agency and/or between Agency components and DHHS, OMB, and congressional staff; (4) provides overall financial-based analyses and fiduciary review for senior HRSA management in order to assure appropriate workforce planning, funds control guidance, and analytical technical assistance in all phases of the budgetary process; and (5) develops the long-range program and financial plan for the Agency in collaboration with the Office of Planning and Evaluation, the Office of Legislation, and other administrative Agency components.

Division of Financial Policy and Controls (RB2)

(1) Provides leadership to define the control environment with senior HRSA management to perform risk assessments identifying the most significant areas necessary for internal control placements; (2) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (3) coordinates the development and improvement of HRSA's financial systems with the UFMS; (4) samples obligation documents and payment requests from a variety of private sector and Government sources to determine the validity and legality of the requests; (5) compiles and submits a variety of cash management and travel reports required by the Department of the Treasury and various other outside agencies; (6) serves as liaison with all HRSA Bureau/Office components and outside customers to provide financial information, resolve problems, and provide information on payment, and disbursement issues; (7) analyzes internal reports to provide management information on special interest topics; (8) develops needs assessment for financial management training based on Government-Wide and DHHS standards; and (9) assures Treasury requirements and OMB suggestions for best practices are implemented in training plan for Agency-wide use.

Section RB–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

Chapter RS—Office of Management

Section RS–10, Organization

Rename the Office of Administration and Financial Management (RS) as the Office of Management (RS) and amend the organization and functional statements to reflect the realignment of the Division of Financial Management (RS2) functions to the newly established Office of Financial Management.

Delete in its entirety and replace with the following:

The Office of Management (OM) is headed by an Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Office of Management includes the following components:

(1) Office of the Associate Administrator (RS);

(2) Division of Management Services (RS1);

(3) Division of Workforce Management (RS3);

(4) Division of Procurement Management (RS4); and

(5) Division of Policy Review and Coordination (RS7).

Section RS–20, Functions

(1) Delete the functional statement for the Division of Financial Management (RS2) and move the function to the newly established Office of Financial Management; (2) Delete the functional statements for the Office of Administration and Financial Management (RS), Division of Management Services (RS1) and the Division of Policy Review and Coordination (RS7) and replace in their entireties; and (3) establish the Division of Workforce Management (RS3).

Office of the Associate Administrator (RS)

Provides Agency-wide leadership, program direction, and coordination to all phases of management. Specifically, the Office of Management: (1) Provides management expertise and staff advice and support to the Administrator in program and policy formulation and execution; (2) manages the Agency-wide Contingency of Operations (COOP) program; (3) provides administrative management services HRSA-wide including personnel, financial, property, space planning, safety, physical security, and general administrative services; (4) conducts Agency-wide workforce analysis studies and surveys; (5) plans, directs, and coordinates the Agency's activities in the areas of human resources management, including labor relations, personnel security, performance and alternative

dispute resolution; (6) directs and coordinates the development of policy and regulations; (7) oversees the development of annual operating objectives and coordinates HRSA work planning and appraisals; (8) directs and coordinates the Agency's organization, functions and delegations of authority programs; (9) plans, directs, and coordinates the Agency's activities in the areas of procurement management; (10) oversees and coordinates the implementation of directives and policies relating to the Privacy Act; (11) plans, directs and coordinates the Agency's competitive sourcing program; (12) administers the Agency's Executive Secretariat and committee management functions; (13) serves as Chief Travel Official for the Agency; and (14) serves as Deputy Ethics Counselor.

Division of Management Services (RS1)

(1) Provides administrative management services HRSA-wide including personnel, financial, property, space planning, safety, physical security, and general administrative services; (2) ensures implementation of statutes, Executive Orders, and regulations related to official travel, transportation, and relocation; (3) provides oversight for the HRSA travel management program involving use of travel management services/systems, passenger transportation, and travel charge cards; (4) provides planning, management and oversight of all interior design projects, move services and furniture requirements; (5) develops space and furniture standards and related policies; (6) provides analysis of office space requirements required in supporting decisions relating to the acquisition of commercial leases and manages the furniture inventory; (7) provides advice, counsel, direction, and support to employees to fulfill the Agency's primary safety responsibility of providing a workplace free from recognizable safety and health concerns; (8) manages, controls, and/or coordinates all matters relating to mail management within HRSA, including, developing and implementing procedures for the receipt, delivery, collection, and dispatch of mail; (9) maintains overall responsibility for the HRSA Forms Management Program that includes establishing internal controls to assure conformity with Departmental policies and standards, including adequate systems for reviewing, clearing, costing, storing and controlling forms; (10) provides advice and guidance for the establishment or modification of administrative delegations of authority; (11) contributes to the analysis, development and implementation of Agency-wide administrative policies through coordination with relevant Agency program components and other related sources; (12) manages the Agency-wide Contingency of Operations (COOP) program; (13) provides advice and guidance for the establishment or modification of program delegations of authority; and (14) oversees and coordinates the implementation of directives and policies relating to the Privacy Act.

Division of Workforce Management (RS3)

(1) Conducts Agency-wide workforce analysis studies and surveys; (2) develops comprehensive workforce strategies that meet the requirements of the President's Management Agenda, programmatic needs of HRSA, and the governance and management needs of HRSA leadership; (3) evaluates employee development practices to develop and enhance strategies to ensure HRSA retains a cadre of public health professionals and reduces risks associated with turnover in mission critical positions; (4) provides advice and guidance for the establishment or modification of organization structures and functions; (5) manages ethics and personnel security programs; (6) administers the Agency's performance management programs, including the SES Performance Review Board; (7) manages quality of work life, flexiplace, and incentive and honor awards programs; (8) coordinates with the service provider the provision of human resources management, working with the service provider to communicate human resources requirements and to monitor the provider's performance; (9) directs and serves as a focal point for the Agency's intern and mentoring programs; and (10) manages the Alternative Dispute Resolution Program.

Division of Procurement Management (RS4)

(1) Provides leadership in the planning, development, and implementation of policies and procedures for contracts; (2) exercises the sole responsibility within HRSA for the award and management of contracts; (3) provides advice and consultation of interpretation and application of the Department of Health and Human Services policies and procedures governing contracts management; (4) develops operating procedures and policies for the Agency's contracts programs; (5) establishes standards and guides for and evaluates contracts operations throughout the Agency; (6) coordinates the Agency's positions and actions with respect to the audit of contracts; (7) maintains liaison directly with or through Agency Bureaus or Offices with contractors, other organizations, and various components of the Department; and (8) provides leadership, guidance, and advice on the promotion of the activities in HRSA relating to procurement and material management governed by the Small Business Act of 1958, Executive Order 11625, and other statutes and national policy directives for augmenting the role of private industry, and small and minority businesses as sources of supply to the Government and Government contractors.

Division of Policy Review and Coordination (RS7)

(1) Advises the Administrator and other key Agency officials on cross-cutting policy issues and assists in the identification and resolution of cross-cutting policy issues and problems; (2) establishes and maintains tracking systems that provide Agency-wide coordination and clearance of policies, regulations and guidelines; (3) plans, organizes and directs the Agency's Executive Secretariat with primary responsibility for preparation and management of written correspondence; (4) arranges briefings for Department officials on critical policy issues and oversees the development of necessary briefing documents; (5) administers administrative early alert system for the Agency to assure senior Agency officials are informed about administrative actions and opportunities; (6) coordinates the preparation of proposed rules and regulations relating to Agency programs and coordinates Agency review and comment on other Department regulations and policy directives that may affect the Agency's programs; (7) manages and maintains a records management program for the Agency; (8) manages the intra- and interagency agreements process; (9) oversees and coordinates the Agency's committee management activities; and (10) coordinates the review and publication of **Federal Register** notices.

Section RS–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon the date of signature.

Dated: April 6, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–7305 Filed 4–17–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: April 20, 2007.

Time: 9:30 a.m. to 5 p.m.

Agenda: Among the topics proposed for discussion are: (1) NIH Director's update; (2) presentation and discussion on NIH Diversity in Research; (3) presentation on Clinical and Community Cancer Centers; (4) NIH communications update; (5) update on the NIH Office of Portfolio Analysis and Strategic Initiatives; (6) discussion on the Council's next steps and priority topics; and (7) public comment.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Jennifer E. Gorman, NIH Public Liaison/COPR Coordinator, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 5B64, Bethesda, MD 20892, (301) 435–448, *gormanj@od.nih.gov.*

This meeting is being published less than 15 days prior to the meeting due to timing limitations imposed by administrative matters.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.copr.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS).

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1902 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center on Minority Health and Health Disparities Special Emphasis Panel Loan Repayment Program for Health Disparities Research-Panel C.

Date: May 20, 2007.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6706 Democracy Blvd., Suite 800, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lorrita Watson, PhD, National Center on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892–5465, (301) 402–1366, *watsonl@ncmhd.nih.gov.*

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1890 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel Exploratory Developmental Alcohol Research Center Review.

Date: May 30, 2007.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Philippe Marmillot, PhD, Scientific Review Administrator, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Room 3045, Bethesda, MD 20892, 301–443–2861, *marmillotp@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS).

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1889 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Respiratory Distress in Newborns and Its Relationship to B Streptococcal Colonization.

Date: May 10, 2007.

Time: 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435–6902, *khanh@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1891 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Longitudinal Study Contract.

Date: April 25, 2007.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Wilbur C. Hadden, PhD, Health Science Administrator, National Institute on Aging, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, *haddenw@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1892 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Design, Synthesis and Preclinical Testing of Potential Treatment Agents for Drug Addiction.

Date: May 8, 2007.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Jury's Washington Hotel, 1500 New Hampshire Avenue, Washington, DC 20036.

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892–8401, (301) 435–1389, *ms80x@nih.gov*.

Name of Committee: National Institute on Drug Abuse Initial Review Group Health Services Research Subcommittee.

Date: June 5–6, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Meenaxi Hiremath, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Blvd., Suite 220, MSC 8401, Bethesda, MD 20892, 301–402–7964, *mh392g@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS).

Dated: April 10, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1893 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

Date: May 30–31, 2007.

Open: May 30, 2007, 3:30 p.m. to 4 p.m.

Agenda: To review procedures and discuss policy.

Place: Intercontinental Toronto Centre, 225 Front Street West, Toronto, ON.

Closed: May 30, 2007, 4 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Intercontinental Toronto Centre, 225 Front Street West, Toronto, ON.

Closed: May 31, 2007, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Intercontinental Toronto Centre, 225 Front Street West, Toronto, ON.

Contact Person: John F. Connaughton, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 916, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797. *connaughtonj@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Subcommittee.

Date: June 27–28, 2007.

Open: June 27, 2007, 2 p.m. to 2:30 p.m.

Agenda: To review procedures and discuss policy.

Place: Crystal City Courtyard by Marriott, 2899 Jefferson Davis Hwy, Arlington, VA 22202.

Closed: June 27, 2007, 2:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal City Courtyard by Marriott, 2899 Jefferson Davis Hwy, Arlington, VA 22202.

Closed: June 28, 2007, 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal City Courtyard by Marriott, 2899 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Neal A. Musto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 751, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7798, *muston@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1894 Filed 4–17–07; 8:45am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Commission on Digestive Diseases, June 18, 2007, 9 a.m. to June 19, 2007, 12 p.m., Sheraton Crystal City, 1800 Jefferson Davis Highway (Rt. 1), Grand Ballroom C, Arlington, VA 22202 which was published in the **Federal Register** on March 28, 2007, 72 FR 14597.

To elaborate on times and dates of the meeting: June 18, 2007 from 9 a.m. until 5 p.m. and on June 19, 2007 from 9 a.m. until 12 noon. The meeting is open to the public.

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1898 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Mechanisms of Viral Innate Immunity.

Date: May 11, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Room 4206, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Jo Ann S. Rinaudo, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–5658, *rinaudoj@mail.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Tuberculosis Epidemiology.

Date: May 15, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Room 3258, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Michelle M. Timmerman, PhD, Scientific Review Administrator, Scientific Review Program, National Institutes of Health/NIAID, Room 3258, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–451–4573, *timmermanm@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Molecular and Cellular Basis of Thymus Function.

Date: May 15, 2007.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Room 3120, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Lynn Rust, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3120, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 402–3938, *lr228v@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1899 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: May 18, 2007.

Open: 8:30 a.m. to 12 p.m.

Agenda: Approval of Minutes, Director's Report.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, 6th Floor, Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, 6th Floor, Room 10, Bethesda, MD 20892.

Contact Person: Norman S. Braveman, PhD, Assistant to the Director, NIH–NIDCR, Building 31, Rm. 5B55, Bethesda, MD 20892, 301 594–2089, *norman.braveman@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 10, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1900 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Viral and Cellular Responses to Severe Influenza Infection.

Date: May 8, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Mini Paulose-Murphy, PhD, Scientific Review Administrator, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 3127, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2640, *murphym@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 10, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1901 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel, R03/R21 SEP.

Date: July 11, 2007.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Zoe E. Huang, MD, Health Science Administrator, Extramural Programs, National Library of Medicine, Rockledge 1 Building, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1896 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Library of Medicine Special Emphasis Panel, July 11, 2007, 8:30 a.m. to July 11, 2007, 5 p.m., Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015 which was published in the **Federal Register** on March 28, 2007, 72 FR 14599.

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1897 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–04–077: Improving Functional Outcomes.

Date: April 25, 2007.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John P. Holden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, *holdenjo@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Renal and Urological Studies Integrated Review Group, Urologic and Kidney Development and Genitourinary Diseases Study Section.

Date: May 15–16, 2007.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Daniel F. McDonald, PhD, Scientific Review Administrator, Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Genomics, Computational Biology and Technology Study Section.

Date: May 31– June 1, 2007.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Camilla E. Day, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7890, Bethesda, MD 20892, (301) 435–1037, *dayc@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 11, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1895 Filed 4–17–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Agency Information Collection Activities: Approval of Commercial Gaugers and Accreditation of Commercial Laboratories

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Accreditation of Commercial Testing Laboratories and Approval of Commercial Gaugers. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments form the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (72 FR 7445) on February 15, 2007, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before May 18, 2007.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Homeland Security/ Customs and Border Protection, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: CBP encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the Proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Accreditation of Commercial Testing Laboratories; Approval of Commercial Gaugers.

OMB Number: 1651–0053.

Form Number: None.

Abstract: The Accreditation of Commercial Testing Laboratories and the Approval of Commercial Gaugers are used by individuals or businesses desiring CBP approval to measure bulk products or analyze importations. This recognition is required of businesses wishing to perform such work on imported merchandise.

Current Actions: This submission is being submitted to extend the expiration date with no change to the burden hours.

Type of Review: Extension (without change).

Affected Public: Businesses, Institutions.

Estimated Number of Respondents: 250.

Estimated Time per Respondent: 1 hour and 48 minutes.

Estimated Total Annual Burden Hours: 450.

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: April 11, 2007.

Tracey Denning,

Agency Clearance Officer, Information Services Branch.

[FR Doc. E7–7327 Filed 4–17–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Agency Information Collection Activities: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Producers

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Producers. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended without a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (72 FR 7445) on February 15, 2007, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before May 18, 2007.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Homeland Security/Customs and Border Protection, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: CBP encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the Proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Distribution of Continued Dumping and Subsidy Offset to Affected Domestic Producers.

OMB Number: 1651–0086.

Form Number: N/A.

Abstract: The collection of information is required to implement the duty preference provisions of the Continued Dumping and Subsidy Offset Act of 2000, by prescribing the administrative procedures under which anti-dumping and countervailing duties are assessed on imported products.

Current Actions: This submission is being submitted to extend the expiration date with a change in the burden hours.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 2000.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 2000 hours.

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: April 11, 2007.

Tracey Denning,

Agency Clearance Officer, Information Services Branch.

[FR Doc. E7–7328 Filed 4–17–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Reviews of Seven Wildlife Species and Two Plant Species in the Mountain-Prairie Region

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of review; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), initiate 5-year reviews of seven wildlife species—Canada lynx (*Lynx canadensis*), grizzly bear (*Ursus arctos horribilis*) (as listed in the lower 48-States excluding the Greater Yellowstone Area population; see table 1), bonytail chub (=bonytail) (*Gila elegans*), humpback chub (*Gila cypha*), Colorado pikeminnow (=squawfish) (*Ptychocheilus lucius*), razorback sucker (*Xyrauchen texanus*), and Uncompahgre fritillary butterfly (*Boloria acrocnema*); and two plant species—*Howellia aquatilis* (water howellia) and *Astragalus desereticus* (Deseret milk-vetch)—in the Mountain-Prairie Region under the Endangered Species Act of 1973, as amended (Act). We conduct 5-year reviews to ensure that our classification of each species as threatened or endangered on the List of Endangered and Threatened Wildlife and Plants is accurate. A 5-year review is an assessment of the best scientific and commercial data available at the time of the review.

DATES: To allow us adequate time to conduct our review, we must receive your information no later than June 18, 2007. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information and review the

information that we receive on these species, see ''Public Solicitation of New Information.''

FOR FURTHER INFORMATION CONTACT: For species-specific information, contact the appropriate person under ''Public Solicitation of New Information.''

SUPPLEMENTARY INFORMATION:

Why Do We Conduct a 5-Year Review?

Section 4(c)(2)(A) of the Act requires that we conduct a review of listed species at least once every 5 years. We are then, under section 4(c)(2)(B) and the provisions of subsections (a) and (b), to determine, on the basis of such a review, whether or not any species should be removed from the List of Endangered and Threatened Wildlife and Plants (delisted), or reclassified from endangered to threatened (downlisted), or reclassified from threatened to endangered (uplisted). The 5-year review is an assessment of the best scientific and commercial data available at the time of the review. Therefore, we are requesting submission of any new information (best scientific and commercial data) on these species since they were originally listed.

For each species, if its present classification is not consistent with the best scientific and commercial information available, we will recommend whether or not a change is warranted in the Federal classification of the species. Any change in Federal classification would require a separate rulemaking process.

Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently under active review. This notice announces our active review of the species in Table 1.

TABLE 1.—SUMMARY OF LISTING INFORMATION, SEVEN WILDLIFE SPECIES AND TWO PLANT SPECIES IN THE MOUNTAIN-PRAIRIE REGION

Common name	Scientific name	Status	Where listed	Final listing rule
ANIMALS:				
Bonytail chub	*Gila elegans*	Endangered	Entire	45 FR 27710; 04/23/1980.
Canada lynx	*Lynx canadensis*	Threatened	CO, ID, ME, MI, MN, MT, NH, NY, OR, UT, VT, WA, WI, WY.	65 FR 16051; 03/24/2000.
Colorado pikeminnow	*Ptychocheilus lucius*	Endangered	Entire, except Salt and Verde R. drainages, AZ.	39 FR 1175; 01/04/1974.
Colorado pikeminnow	*Ptychocheilus lucius*	Experimental population.	Salt and Verde R. drainages, AZ.	50 FR 30188; 07/24/1985.
Grizzly bear	*Ursus arctos horribilis*	Threatened	U.S.A., conterminous (lower 48) States*.	40 FR 31734; 07/28/1975.
Grizzly bear	*Ursus arctos horribilis*	Experimental population.	U.S.A. (portions of ID and MT; see 50 CFR 17.84(l)).	65 FR 69623; 11/17/2000.
Humpback chub	*Gila cypha*	Endangered	Entire	39 FR 1175; 01/04/1974.
Razorback sucker	*Xyrauchen texanus*	Endangered	Entire	56 FR 54957; 10/23/1991.
Uncompahgre fritillary (Butterfly)	*Boloria acrocnema*	Endangered	Entire	56 FR 28712; 06/24/1991.
PLANTS:				
Deseret milk-vetch	*Astragalus desereticus*	Threatened	Entire	64 FR 56590; 10/20/1999.
Water howellia	*Howellia aquatilis*	Threatened	Entire	59 FR 35860; 07/14/1994.

*U.S.A., conterminous (lower 48) States, except: (1) Where listed as an experimental population; and (2) that portion of Idaho east of Interstate Highway 15 and north of U.S. Highway 30; that portion of Montana east of Interstate Highway 15 and south of Interstate Highway 90; that portion of Wyoming south of Interstate Highway 90, west of Interstate Highway 25, Wyoming State Highway 220, and U.S. Highway 287 south of Three Forks (at the 220 and 287 intersection), and north of Interstate Highway 80 and U.S. Highway 30. See 17.40(b).

What Information Do We Consider in Our Review?

In our 5-year review, we consider all new information available at the time of the review. These reviews will consider the best scientific and commercial data that have become available since the original listing determination or most recent status review of each species, such as—(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics; (B) Habitat conditions, including but not limited to amount, distribution, and suitability; (C) Conservation measures that have been implemented to benefit the species; (D) Threat status and trends (see five factors under heading ''How do we determine whether a species is endangered or threatened?''); and (E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List of Endangered and Threatened Wildlife and Plants, and improved analytical methods.

Public Solicitation of New Information

We request any new information concerning the status of the wildlife species Canada lynx, grizzly bear, bonytail chub, humpback chub, Colorado pikeminnow, razorback sucker, and Uncompahgre fritillary butterfly, and of the plant species *Howellia aquatilis* and *Astragalus desereticus.* See ''What Information Do We Consider in Our Review?'' for specific criteria. If you submit information, support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources. We specifically request

information regarding data from any systematic surveys, as well as any studies or analysis of data that may show population size or trends; information pertaining to the biology or ecology of the species; information regarding the effects of current land management on population distribution and abundance; information on the current condition of habitat; and recent information regarding conservation measures that have been implemented to benefit the species. Additionally, we specifically request information regarding the current distribution of populations and evaluation of threats faced by the species in relation to the five listing factors (as defined in section 4(a)(1) of the Act) and the species' listed status as judged against the definition of threatened or endangered. Finally, we solicit recommendations pertaining to the development of or potential updates to recovery plans and additional actions or studies that would benefit these species in the future.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Submit your comments and information on the following species to the corresponding address(es). You also may view information we receive in response to this notice and review, as well as other documentation in our files, at the following locations by appointment, during normal business hours. For more information on a species, contact the corresponding person listed below.

Canada lynx: Mark Wilson, Montana Field Supervisor, U.S. Fish and Wildlife Service, Attention: Canada lynx 5-year Review, 585 Shepard Way, Helena, Montana 59601; telephone (406) 449–5225.

Grizzly bear: Dr. Christopher Servheen, Grizzly Bear Recovery Coordinator, Attention: Grizzly Bear 5-year Review, University Hall, Room #309, University of Montana, Missoula, Montana 59812; telephone (406) 243–4903.

Bonytail chub, humpback chub, Colorado pikeminnow, and razorback sucker: Thomas E. Czapla, PhD, Upper Colorado River Endangered Fish Recovery Program, U.S. Fish and Wildlife Service, Attention: Colorado River Fish 5-year Review, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225; telephone (303) 969–7322, extension 228.

Uncompahgre fritillary butterfly: Al Pfister, Western Colorado Project Leader, U.S. Fish and Wildlife Service, Attention: Uncompahgre fritillary butterfly 5-year Review, 764 Horizon Drive, Building B, Grand Junction, Colorado 81506–3946; telephone (970) 243–2778.

Water howellia: Mark Wilson, Montana Field Supervisor, U.S. Fish and Wildlife Service, Attention: water howellia (*Howellia aquatilis*) 5-year Review, 585 Shepard Way, Helena, Montana 59601; telephone (406) 449–5225.

Astragalus desereticus: Larry Crist, Utah Field Supervisor, U.S. Fish and Wildlife Service, Attention: Deseret milk-vetch (*Astragalus desereticus*) 5-year Review, 2369 West Orton Circle, Suite 50, West Valley City, Utah 84119; telephone (801) 975–3330.

How Are These Species Currently Listed?

Table 1 gives current listing information. Also, the List of Endangered and Threatened Wildlife and Plants (List), which covers all listed species, is in 50 CFR 17.11 (wildlife) and 17.12 (plants). We amend the List by publishing final rules in the **Federal Register**. The List also is available on our Internet site at *http://endangered.fws.gov/wildlife.html#Species.*

Definitions

To help you submit information about the species being reviewed, we provide the following definitions:

(A) *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate, which interbreeds when mature;

(B) *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range; and

(C) *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

How Do We Determine Whether a Species Is Endangered or Threatened?

Section 4(a)(1) of the Act establishes that we determine whether a species is endangered or threatened based on one or more of the five following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

Section 4(a)(1) of the Act requires that our determination be made on the basis of the best scientific and commercial data available.

What Could Happen as a Result of Our Review?

For each species under review, if we find new information that indicates a change in classification may be warranted, we may propose a new rule that could do one of the following:

(a) Reclassify the species from threatened to endangered (uplist);

(b) Reclassify the species from endangered to threatened (downlist); or

(c) Remove the species from the List (delist).

If we determine that a change in classification is not warranted, then this species will remain on the List under its current status.

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 16, 2007.

James J. Slack,

Acting Regional Director, Denver, Colorado.

[FR Doc. E7–7342 Filed 4–17–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

April 12, 2007.

The Department of Labor (DOL) has submitted the following public information collection requests (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained from RegInfo.gov at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number)/e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Mine Safety and Health Administration (MSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316/Fax: 202–395–6974 (these are not a toll-free numbers), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Mine Safety and Health Administration.

Type of Review: Extension without change of currently approved collection.

Title: Certificate of Electrical Training.

OMB Number: 1219–0001.

Form Number: MSHA Form 5000–1.

Type of Response: Reporting.

Affected Public: Private Sector: Business or other for-profit (mining industry).

Number of Respondents: 4,845.

Estimated Number of Annual Responses: 2,294.

Average Response Time: 6 minutes.

Estimated Annual Burden Hours: 138.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $9,257.

Description: MSHA Form 5000–1, Certificate of Electrical Training, is required to be used by instructors for reporting to MSHA the qualification of those persons who have satisfactorily completed a coal mine electrical training program course.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E7–7329 Filed 4–17–07; 8:45 am]

BILLING CODE 4510–43–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meetings

April 10, 2007.

TIME AND DATE: 10:30 a.m., Thursday, April 19, 2007.

PLACE: The Richard V. Backley Hearing Room, 9th Floor, 601 New Jersey Avenue, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *United Mine Workers of America on behalf of Local 1248, District 2* v. *Maple Creek Mining, Inc.,* Docket No. PENN 2002–23–C. (Issues include whether the Administrative Law Judge erred in denying the operator's motion for summary decision on the ground that a withdrawal order issued to the operator pursuant to section 104(b) of the Mine Act could not be contested pursuant to section 105(a), and thus became final for purposes of the compensation provisions of section 111 when it was not contested under section 105(d) within 30 days of its issuance).

The Commission heard oral argument in this matter on March 22, 2007.

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen (202) 434–9950/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 07–1939 Filed 4–16–07; 12:05 pm]

BILLING CODE 6735–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on May 3–5, 2007, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Wednesday, November 15, 2006 (71 FR 66561).

Thursday, May 3, 2007, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: Commission Paper on Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, ''Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors'' (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the Commission paper related to rulemaking to make risk-informed changes to loss-of-coolant accident technical requirements, and related matters.

10:45 a.m.–12:15 p.m.: Digital Instrumentation and Control Systems Matters (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff's activities related to digital instrumentation and control systems, and related matters.

1:15 p.m.–2:45 p.m.: Commission Paper on Staff's Recommendation to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff's recommendation to make a risk-informed and performance-based revision to 10 CFR Part 50, and related matters.

3 p.m.–4:30 p.m.: Status of the Development of an Integrated Long-Term Regulatory Research Plan (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff's activities associated with the development of an integrated long-term regulatory research plan.

4:45 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting. In addition, the Committee will discuss a report on the proposed revision to 10 CFR 50.46 LOCA criteria for fuel cladding materials.

Friday, May 4, 2007, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: ACRS Member's Issues Associated with the Technology-Neutral Framework for Future Plant Licensing (Open)—The Committee will discuss and decide on individual member's issues associated with the technology-neutral framework for future plant licensing.

10:45 a.m.–11:45 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings. Also, it will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, including anticipated workload and member assignments.

11:45 a.m.–12 Noon: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

1 p.m.–2:30 p.m.: Discussion of Topics for Meeting with the NRC Commissioners (Open)—The Committee will discuss the following topics scheduled for discussion during the meeting with the NRC Commissioners on June 7, 2007: Framework for Future Plant Licensing, Digital I&C Activities, License Renewal/Extended Power Uprates, Human Reliability Analysis Models, and Staff's Report on Status of the 10 CFR 50.46 Rulemaking.

2:45 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports.

Saturday, May 5, 2007, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–12:30 p.m.: Preparation of ACRS Reports (Open)—The Committee will continue discussion of proposed ACRS reports.

12:30 p.m.–1:00 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 2, 2006 (71 FR 58015). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Sam Duraiswamy, Cognizant ACRS staff (301–415–7364), between 7:30 a.m. and 4 p.m., (ET).

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/* (ACRS & ACNW Mtg schedules/agendas).

Videoteleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the videoteleconferencing link. The availability of videoteleconferencing services is not guaranteed.

Dated: April 4, 2007.

Andre L. Bates

Advisory Committee Management Officer.

[FR Doc. E7–7368 Filed 4–17–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Subcommittee Meeting on Thermal-Hydraulic Phenomena; Revised

The ACRS Subcommittee meeting on Thermal-Hydraulic Phenomena scheduled for April 19–20, 2007 has been *rescheduled to May 23–24, 2007 at 8:30 a.m. in Room T–2B3, at 11545 Rockville Pike, Rockville, Maryland.*

The entire meeting will be open to public attendance, with the exception of portions that may be closed to discuss General Electric proprietary information pursuant to 5 U.S.C. 552b(c)(4).

The Subcommittee will review the staff evaluation of the MELLLA+, GE Methods, and GE DSS–CD Topical Reports. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Notice of this meeting was published in the **Federal Register** on Tuesday, April 3, 2007, (72 FR 15914). All other items pertaining to this meeting remain the same as previously published.

For further information contact: Mr. Ralph Caruso, Senior Staff Engineer (telephone 301–415–8065 or e-mail: *rxc@nrc.gov*) between 7:30 a.m. and 4:15 p.m. (ET).

Dated: April 12, 2007.

Cayetano Santos,

Acting Branch Chief, ACRS.

[FR Doc. E7–7369 Filed 4–17–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Preclosure Safety Analysis—Level of Information and Reliability Estimation; Availability of Final Interim Staff Guidance Document

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance; correction.

SUMMARY: This document corrects a notice, appearing in the **Federal Register** on March 22, 2007 (72 FR 13534), that announces the availability of a final interim staff guidance document on ''Preclosure Safety

Analysis—Level of Information and Reliability Estimation.'' This action is necessary to correct typographical errors.

FOR FURTHER INFORMATION, CONTACT: Jon Chen, Project Manager, Division of High-Level Waste Repository Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 [Telephone: (301) 415–5526; fax number: (301) 415–5399; e-mail: *jcc2@nrc.gov*.]

SUPPLEMENTARY INFORMATION: On page 13534, in the middle column, in the first paragraph, last sentence, ''waste at a geologic repository'' is changed to ''waste geologic repository.''

On page 13536, in the middle column, in the fourth complete paragraph, lines 4–5, ''DOE should to consider'' is changed to read ''DOE should consider.''

On page 13536, in the middle column, in the fourth complete paragraph, lines 7–8, ''DOE should to provide'' is changed to read ''DOE should provide.''

On page 13537, in the third column, in the eighth complete paragraph, lines 1–2, ''Lines 445: Though 453: λ was changed to, to distinguish this quantity'' is changed to ''Lines 445 through 453: λ was changed to p̂ to distinguish this quantity.''

Dated at Rockville, Maryland, this 11th day of April, 2007.

For the Nuclear Regulatory Commission.

N. King Stablein,

Chief Project-Management Branch B, Division of High-Level Repository Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E7–7373 Filed 4–17–07; 8:45 am]

BILLING CODE 7590–01–P

TRADE REPRESENTATIVE

[Docket No. WTO/DS–360]

WTO Dispute Settlement Proceeding Regarding India—Additional and Extra Additional Duties on Imports

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice that on March 6, 2007, in accordance with the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement), the United States requested consultations regarding additional and extra additional duties India applies to imports from the United States. India applies these duties to products that include, but are not limited to, imports of wines and distilled spirits. That request may be found at *www.wto.org* contained in a document designated as WT/DS360/1. USTR invites written comments from the public concerning the issues raised in this dispute.

DATES: Although USTR will accept any comments received during the course of the consultations, comments should be submitted on or before May 7, 2007 to be assured of timely consideration by USTR.

ADDRESSES: Comments should be submitted (i) electronically, to *FR0706@ustr.eop.gov*, with ''India Alcohol Duties (DS360)'' in the subject line, or (ii) by fax, to Sandy McKinzy at (202) 395–3640, with a confirmation copy sent electronically to the electronic mail address above, in accordance with the requirements for submission set out below.

FOR FURTHER INFORMATION CONTACT: Amy A. Karpel, Assistant General Counsel, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC, (202) 395–3150.

SUPPLEMENTARY INFORMATION: Section 127(b) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)) requires that notice and opportunity for comment be provided after the United States submits or receives a request for the establishment of a WTO dispute settlement panel. In an effort to provide additional opportunity for comment, USTR is providing notice that consultations have been requested pursuant to the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* (''DSU''). If such consultations should fail to resolve the matter and a dispute settlement panel is established pursuant to the DSU, such panel, which would hold its meetings in Geneva, Switzerland, would be expected to issue a report on its findings and recommendations within nine months after it is established.

Major Issues Raised by the United States

On March 6, 2007, the United States requested consultations with India regarding additional and extra additional duties India applies to imports from the United States. India applies these duties to products that include, but are not limited to, imports of wines and distilled spirits. These duties appear to subject imports to ordinary customs duties or other duties or charges in excess of those in India's WTO Tariff Schedule. These duties include the following, as well as any amendments and related or implementing measures:

- Sections 2 and 3, and First Schedule, of the Customs Tariff Act, 1975; (''basic customs duty,'' ''additional duty'' and ''extra additional duty'').
- Section 12 of the Customs Act, 1962 (''basic customs duty'').
- Customs Notification No. 5/2004 (January 8, 2004) (''basic customs duty'' *inter alia* on spirits);
- Customs Notification No. 20/1997 (March 1, 1997) (''basic customs duty'' *inter alia* on wine);
- Customs Notification No. 32/2003 (March 1, 2003) (''additional duty'' *inter alia* on wine and spirits); and
- Customs Notification No. 19/2006 (March 1, 2006) (''extra additional duty'' *inter alia* on wine and spirits).

As a result of the duties, products from the United States do not appear to be exempt from ordinary customs duties or other charges in excess of those set forth in India's WTO Tariff Schedule and appear to be accorded less favorable treatment than that provided for in India's WTO Tariff Schedule. Even if these duties were considered to be internal taxes applied at the time of importation, the duties appear to subject imports from the United States to internal taxes in excess of those applied to like domestic products or directly competitive or substitutable domestic products

USTR believes these measures are inconsistent with India's obligations under Article II:1(a) and (b), Articles III:2 and III:4 of the *General Agreement on Tariffs and Trade 1994.*

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in the dispute. Comments should be submitted (i) electronically, to *FR0706@ustr.eop.gov*, with ''India Alcohol Duties (DS360)'' in the subject line, or (ii) by fax, to Sandy McKinzy at (202) 395–3640, with a confirmation copy sent electronically to the electronic mail address above.

USTR encourages the submission of documents in Adobe PDF format as attachments to an electronic mail. Interested persons who make submissions by electronic mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. Similarly, to the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Comments must be in English. A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the commenter. Confidential business information must be clearly designated as such and ''Business Confidential'' must be marked at the top and bottom of the cover page and each succeeding page. Persons who submit confidential business information are encouraged also to provide a non-confidential summary of the information.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must clearly so designate the information or advice;

(2) Must clearly mark the material as ''Submitted In Confidence'' at the top and bottom of the cover page and each succeeding page; and

(3) Is encouraged to provide a non-confidential summary of the information or advice.

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a file on this dispute settlement proceeding, accessible to the public, in the USTR Reading Room, which is located at 1724 F Street, NW., Washington, DC 20508. The public file will include non-confidential comments received by USTR from the public with respect to the dispute; if a dispute settlement panel is convened or in the event of an appeal from such a panel, the U.S. submissions, the submissions, or non-confidential summaries of submissions, received from other participants in the dispute; the report of the panel; and, if applicable, the report of the Appellate Body. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the public file (Docket WTO/DS–360, India Alcohol Duties Dispute) may be made by calling the USTR Reading Room at (202) 395–6186.

Daniel Brinza,

Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. E7–7376 Filed 4–17–07; 8:45 am]

BILLING CODE 3190–W7–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

April 19, 2007 Public Hearing

OPIC's Sunshine Act notice of its Public Hearing in Conjunction with each Board meeting was published in the **Federal Register** (Volume 72, Number 59, Page 14627) on March 29, 2007. No requests were received to provide testimony or submit written statements for the record; therefore, OPIC's public hearing scheduled for 2 PM, April 19, 2007 in conjunction with OPIC's April 26, 2007 Board of Directors meeting has been cancelled.

Contact Person For Information: Information on the hearing cancellation may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 218–0136, or via e-mail at *cdown@opic.gov*.

Dated: April 16, 2007.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 07–1945 Filed 4–16–07; 1:53 pm]

BILLING CODE 3210–01–M

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Self-Employment and Substantial Service Questionnaire; OMB 3220–0138. Section 2 of the Railroad Retirement Act (RRA) provides for payment of annuities to qualified employees and their spouses. In order to receive an age and service annuity, Section 2(e)(3) states that an applicant must stop all railroad work and give up any rights to return to such work. However, applicants are not required to stop non-railroad work or self-employment.

The RRB considers some work claimed as ''self-employment'' to actually be employment for an employer. Whether the RRB classifies a particular activity as self-employment or as work for an employer depends upon the circumstances of each case. These circumstances are prescribed in 20 CFR part 216.

Under the 1988 amendments to the RRA, an applicant is no longer required to stop work for a ''Last Pre-Retirement Nonrailroad Employer'' (LPE). However, section 2(f)(6) of the RRA requires that a portion of the employee's Tier II benefit and supplemental annuity be deducted for earnings from a ''LPE'' employer.

''LPE'' is defined as the last person, company or institution with whom the employee or spouse applicant was employed concurrently with, or after, the applicant's last railroad employment and before their annuity beginning date. If a spouse never worked for a railroad, the LPE employer is the last person for whom he or she worked.

The RRB currently utilizes Form AA–4, Self-Employment and Substantial Service Questionnaire, when an applicant claims to be self-employed to obtain information needed to determine if the applicant's work is LPE, railroad service or self-employment. If the work is self-employment, the questionnaire identifies any months in which the applicant did not perform substantial service. One response is requested of each respondent. Completion is voluntary. However, failure to complete the form could result in the nonpayment of benefits.

The RRB proposes editorial and formatting changes to Form AA–4. Other non-burden impacting changes include dividing current items that currently contain multiple questions into separate items with Yes/No responses and skip patterns. Checklists have also been added to many items to obtain more standardized responses. Currently most items cite the possible options only as examples to prompt the applicant.

The completion time for the AA–4 is estimated at between 40 and 70 minutes. The RRB estimates that approximately 600 AA–4's are completed annually.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to

Charles.Mierzwa@RRB.GOV. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or send an e-mail to *Ronald.Hodapp@RRB.GOV*. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. E7–7303 Filed 4–17–07; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55612; File No. 4–536]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing of Proposed Plan for the Allocation of Regulatory Responsibilities Between the Chicago Board Options Exchange, Incorporated and the National Association of Securities Dealers, Inc.

April 10, 2007.

Pursuant to Section 17(d) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 17d–2 thereunder,[2] notice is hereby given that on April 5, 2007, the Chicago Board Options Exchange, Incorporated (''CBOE'') and the National Association of Securities Dealers, Inc. (''NASD'') (together with the CBOE, the ''Parties'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') a plan for the allocation of regulatory responsibilities with respect to the CBOE Stock Exchange, LLC (''CBSX''), dated April 4, 2007 (''17d–2 Plan''). The Commission is publishing this notice to solicit comments on the 17d–2 Plan from interested persons.

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization (''SRO'') registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[4] Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (''common members''). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[5] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[6] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[7] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[8] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[9] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. Proposed Plan

The Commission recently approved proposed rule changes submitted by CBOE to establish the CBSX as a facility of CBOE.[10] CBSX is a fully automated marketplace for trading of non-option securities by CBOE members.

Pursuant to the proposed 17d–2 Plan, NASD would assume certain examination and enforcement responsibilities for common members with respect to certain applicable laws, rules, and regulations. The proposed 17d–2 Plan is intended to reduce regulatory duplication, with respect to CBSX, for firms that are common members of both CBOE and NASD.[11]

The text of the plan delineates regulatory responsibilities with respect to the Parties, including responsibility for CBOE rules applicable to the CBSX. Included in the proposed plan is an exhibit (the ''CBOE Certification of Common Rules,'' referred to herein as the ''Certification'') that lists every CBOE rule, and the federal securities laws, rules, and regulations thereunder, for which NASD would bear responsibility under the plan for overseeing and enforcing with respect to common members.

In particular, under the 17d–2 Plan, NASD would assume examination and enforcement responsibility relating to compliance by dual members and persons associated therewith with the rules of CBOE that are substantially similar to the applicable rules of NASD

[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

[3] 15 U.S.C. 78s(g)(1).

[4] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[5] 15 U.S.C. 78q(d)(1).

[6] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[7] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[8] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[9] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

[10] Accordingly, CBOE serves as CBSX's self-regulatory organization and has regulatory responsibility for the activities of CBSX. *See* Securities Exchange Act Release Nos. 55326 (February 21, 2007), 72 FR 8816 (February 27, 2007) (SR–CBOE–2006–106) (relating to a permit program for CBSX); 55389 (March 2, 2007), 72 FR 10575 (March 8, 2007) (SR–CBOE–2006–110) (relating to governance structure of CBSX); and 55392 (March 2, 2007), 72 FR 10572 (March 8, 2007) (SR–CBOE–2006–112) (relating to trading rules for CBSX).

[11] The proposed 17d–2 Plan refers to these common members as ''Dual Members.'' *See* Paragraph 1(c) of the proposed 17d–2 Plan.

(''Common Rules''),[12] as well as any provisions of the federal securities laws and the rules and regulations thereunder delineated in the Certification.[13] Under the plan, CBOE would retain full responsibility for surveillance and enforcement with respect to trading activities or practices involving CBOE's own marketplace, including, without limitation, CBOE's rules relating to the rights and obligations of market makers; registration pursuant to its unique rules (*i.e.*, non-Common Rules); its duties as a DEA pursuant to Rule 17d–1 under the Act; and any rules that are not Common Rules.

The text of the 17d–2 Plan is as follows:

Agreement Between NASD and Chicago Board Options Exchange, Incorporated Pursuant to Rule 17d–2 Under the Securities Exchange Act of 1934

This Agreement, by and between the National Association of Securities Dealers, Inc. (''NASD'') and the Chicago Board Options Exchange, Incorporated (''CBOE''), is made this 4th day of April, 2007 (the ''Agreement''), pursuant to section 17(d) of the Securities Exchange Act of 1934 (the ''Exchange Act'') and rule 17d–2 thereunder which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. NASD and CBOE may be referred to individually as a ''party'' and together as the ''parties.''

Whereas, NASD and CBOE desire to reduce duplication in the examination of their Dual Members (as defined herein) and in the filing and processing of certain registration and membership records as it relates to the CBOE Stock Exchange, LLC; and

Whereas, NASD and CBOE desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d–2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the ''SEC'' or ''Commission'') for its approval.

Now, therefore, in consideration of the mutual covenants contained hereinafter, NASD and CBOE hereby agree as follows:

1. *Definitions.* Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:

(a) *''CBOE Rules''* or *''NASD Rules''* shall mean the rules of the CBOE or NASD, respectively, as the rules of an exchange or association are defined in Exchange Act section 3(a)(27).

(b) *''Common Rules''* shall mean the CBOE Rules that are substantially similar to the applicable NASD Rules in that examination for compliance with such rules would not require NASD to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of the rule, or a Dual Member's activity, conduct, or output in relation to such rule.

(c) *''Dual Members''* shall mean those CBOE members that are also members of NASD and the associated persons therewith.

(d) *''Effective Date''* shall have the meaning set forth in paragraph 14.

(e) *''Enforcement Responsibilities''* shall mean the conduct of appropriate proceedings, in accordance with the NASD Code of Procedure (the Rule 9000 Series) and other applicable NASD procedural rules, to determine whether violations of pertinent laws, rules or regulations have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under the NASD's Code of Procedure and sanctions guidelines.

(f) *''Regulatory Responsibilities''* shall mean the examination responsibilities and Enforcement Responsibilities relating to compliance by the Dual Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on *Exhibit 1* attached hereto.

2. *Regulatory and Enforcement Responsibilities.* NASD shall assume Regulatory Responsibilities and Enforcement Responsibilities for Dual Members. Attached as *Exhibit 1* to this Agreement and made part hereof, CBOE furnished NASD with a current list of Common Rules and certified to NASD that such rules are substantially similar to the corresponding NASD rule (the ''Certification''). NASD hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in either the rules of CBOE or NASD, CBOE shall submit an updated list of Common Rules to NASD for review which shall add CBOE rules not included in the current list of Common Rules that qualify as Common Rules as defined in this Agreement; delete CBOE rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be CBOE rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, NASD shall confirm in writing whether the rules listed in any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term ''Regulatory Responsibilities'' does not include, and CBOE shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) the following:

(a) surveillance and enforcement with respect to trading activities or practices involving CBOE's own marketplace, including without limitation CBOE's rules relating to the rights and obligations of market makers;

(b) registration pursuant to its applicable rules of associated persons (*i.e.*, registration rules that are not Common Rules);

(c) discharge of its duties and obligations as a Designated Examining Authority pursuant to Rule 17d-1 under the Exchange Act; and

(d) any CBOE Rules that are not Common Rules.

3. *Dual Members.* Prior to the Effective Date, CBOE shall furnish NASD with a current list of Dual Members, which shall be updated no less frequently than once each quarter.

4. *No Charge.* There shall be no charge to CBOE by NASD for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as hereinafter provided. NASD shall provide CBOE with ninety (90) days advance written notice in the event NASD decides to impose any charges to CBOE for performing the Regulatory Responsibilities under this Agreement. If NASD determines to impose a charge, CBOE shall have the right at the time of the imposition of such charge to terminate this Agreement; provided, however, that NASD's Regulatory Responsibilities under this Agreement shall continue until the Commission approves the termination of this Agreement.

5. *Reassignment of Regulatory Responsibilities.* Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the Commission, or industry agreement, restructuring the regulatory framework of the securities industry or reassigning Regulatory Responsibilities between self-regulatory organizations.

[12] *See* paragraph 1(b) of the proposed 17d–2 plan (defining Common Rules).

[13] *See* paragraph 1(f) of the proposed 17d–2 plan.

To the extent such action is inconsistent with this Agreement, such action shall supersede the provisions hereof to the extent necessary for them to be properly effectuated and the provisions hereof in that respect shall be null and void.

6. *Notification of Violations.* In the event that NASD becomes aware of apparent violations of any CBOE Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, NASD shall notify CBOE of those apparent violations for such response as CBOE deems appropriate. Apparent violations of all other applicable rules, including violations of the Common Rules, various securities acts, and rules and regulations thereunder, shall be processed by, and enforcement proceedings in respect thereto shall be conducted by NASD as provided hereinbefore; provided, however, that in the event a Dual Member is the subject of an investigation relating to a transaction on the CBOE, CBOE may in its discretion assume concurrent jurisdiction and responsibility. Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

7. *Continued Assistance.* NASD shall make available to CBOE all information obtained by NASD in the performance by it of the Regulatory Responsibilities hereunder in respect to the Dual Members subject to this Agreement. In particular, and not in limitation of the foregoing, NASD shall furnish CBOE any information it obtains about Dual Members which reflects adversely on their financial condition. It is understood that such information is of an extremely sensitive nature and, accordingly, CBOE acknowledges and agrees to take all reasonable steps to maintain its confidentiality. CBOE shall make available to NASD any information coming to its attention that reflects adversely on the financial condition of Dual Members or indicates possible violations of applicable laws, rules or regulations by such firms.

8. *Dual Member Applications.*

(a) Dual Members subject to this Agreement shall be required to submit, and NASD shall be responsible for processing and acting upon all applications submitted on behalf of allied persons, partners, officers, registered personnel and any other person required to be approved by the rules of both CBOE and NASD or associated with Dual Members thereof. Upon request, NASD shall advise CBOE of any changes of allied members, partners, officers, registered personnel and other persons required to be approved by the rules of both CBOE and NASD.

(b) Dual Members shall be required to send to NASD all letters, termination notices or other material respecting the individuals listed in paragraph 8(a).

(c) When as a result of processing such submissions NASD becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a Dual Member, NASD shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep CBOE advised of its actions in this regard for such subsequent proceedings as CBOE may initiate.

(d) Notwithstanding the foregoing, NASD shall not review the membership application, reports, filings, fingerprint cards, notices, or other writings filed to determine if such documentation submitted by a broker or dealer, or a person associated therewith or other persons required to register or qualify by examination meets the CBOE requirements for general membership or for specified categories of membership or participation in the CBOE. NASD shall not review applications or other documentation filed to request a change in the rights or status described in this paragraph 8(d), including termination or limitation on activities, of a member or a participant of the CBOE, or a person associated with, or requesting association with, a member or participant of the CBOE.

9. *Branch Office Information.* NASD shall also be responsible for processing and, if required, acting upon all requests for the opening, address changes, and terminations of branch offices by Dual Members and any other applications required of Dual Members with respect to the Common Rules as they may be amended from time to time. Upon request, NASD shall advise CBOE of the opening, address change and termination of branch and main offices of Dual Members and the names of such branch office managers.

10. *Customer Complaints.* CBOE shall forward to NASD copies of all customer complaints involving Dual Members received by CBOE relating to NASD's Regulatory Responsibilities under this Agreement. It shall be NASD's responsibility to review and take appropriate action in respect to such complaints.

11. *Advertising.* NASD shall assume responsibility to review the advertising of Dual Members subject to the Agreement, provided that such material is filed with NASD in accordance with NASD's filing procedures and is accompanied with any applicable filing fees set forth in NASD Rules. Such review shall be made in accordance with then applicable NASD rules and interpretations. The advertising of Dual Members shall be subject only to compliance with appropriate NASD rules and interpretations.

12. *No Restrictions on Regulatory Action.* Nothing contained in this Agreement shall restrict or in any way encumber the right of either party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against Dual Members, as either party, in its sole discretion, shall deem appropriate or necessary.

13. *Termination.* This Agreement may be terminated by CBOE or NASD at any time upon the approval of the Commission after one (1) year's written notice to the other party, except as provided in paragraph 4.

14. *Effective Date.* This Agreement shall be effective upon approval of the Commission.

15. *Arbitration.* In the event of a dispute between the parties as to the operation of this Agreement, CBOE and NASD hereby agree that any such dispute shall be settled by arbitration in Washington, D.C. in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction.

16. *Separate Agreement.* This Agreement is wholly separate from the multiparty Agreement made pursuant to Rule 17d-2 of the Exchange Act between the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Board Options Exchange, Incorporated, the International Securities Exchange LLC, the National Association of Securities Dealers, Inc., the New York Stock Exchange, LLC, the NYSE Arca, Inc., and the Philadelphia Stock Exchange, Inc. involving the allocation of regulatory responsibilities with respect to common members for compliance with common rules relating to the conduct by broker-dealers of accounts for listed options or index warrants entered into on December 1, 2006, and as may be amended from time to time.

17. *Notification of Members.* CBOE and NASD shall notify Dual Members of this Agreement after the Effective Date by means of a uniform joint notice.

18. *Amendment.* This Agreement may be amended in writing duly approved by each party. All such amendments must be filed with and approved by the

Commission before they become effective.

19. *Limitation of Liability.* Neither NASD nor CBOE nor any of their respective directors, governors, officers or employees shall be liable to the other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by one or the other of NASD or CBOE and caused by the willful misconduct of the other party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by NASD or CBOE with respect to any of the responsibilities to be performed by each of them hereunder.

20. *Relief from Responsibility.* Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d–2 thereunder, NASD and CBOE join in requesting the Commission, upon its approval of this Agreement or any part thereof, to relieve CBOE of any and all responsibilities with respect to matters allocated to NASD pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.

In witness whereof, each party has executed or caused this Agreement to be executed on its behalf by a duly authorized officer as of the date first written above.

National Association Of Securities Dealers, Inc.

By _____

Name:

Title:

Chicago Board Options Exchange, Incorporated

By _____

Name:

Title:

Exhibit 1

CBOE Certification of Common Rules

CBOE hereby certifies that the requirements contained in the CBOE Rules listed below are identical to, or substantially similar to, the NASD or SEC Rules identified.†

CBOE rule(s)	NASD or SEC rule(s)††
4.18 Prevention of the Misuse of Material, Nonpublic Information	Section 15(f) of the Securities Exchange Act of 1934 (Exchange Act).†††
4.20 Anti-Money Laundering Compliance Program	3011 Anti-Money Laundering Compliance Program.
9.3 Registration and Termination of Representatives	1031(a), (b) Registration Requirements 1140(a), (d) Electronic Filing Rules, and NASD By-Laws, Art. V, Sections 2 and 3 Registered Representatives and Associated Persons.
9.3A Continuing Education For Registered Persons	1120 Continuing Education Requirements.
9.4(a) Other Affiliations of Registered Associated Persons	3030 Outside Business Activities of an Associated Person.
9.12 Statements of Accounts to Customers††††	2340 Customer Account Statements.
9.13 Statement of Financial Condition to Customers	Exchange Act Rule 17a–5.
9.16 Restrictions on Pledge and Lending of Customers' Securities	2330(a)–(d) Customers' Securities or Funds.
9.18 Guarantees and Profit Sharing	2330(e) & (f) Customers' Securities or Funds.†††††
9.20 Transfer of Accounts	11870 Customer Account Transfer Contracts.
9.23 Customer Complaints††††††	3110(d) Books and Records.
9.24 Telephone Solicitation	2212 Telemarketing and 3110(g) Books and Records.
9.25 Borrowing From or Lending to Customers	2370 Borrowing From or Lending to Customers.
53.6(c) Duty to Know and Approve Customers	2310 Recommendations to Customers (Suitability) and 3110(c) Books and Records.
53.6(d) Branch Offices of Member Organizations	1021(a) Registration Requirements and IM–1000–4 Branch Offices and Offices of Supervisory Jurisdiction.
53.6(e) Discretionary Accounts	2510 Discretionary Accounts.
53.6(f) Confirmation to Customers	2230 Confirmations and Exchange Act Rule 10b–10.†††††††
53.6(g) Communications to Customers	2210(b) and(d) Communications with the Public and IM–2210–1(6) Guidelines to Ensure That Communications With the Public Are Not Misleading.
53.6(h) Supervision of Accounts	3010(a), (b) Supervision and 3110(c) Books and Records.

† To the extent that any CBOE Rule listed herein makes reference to options, such rule shall be read to apply to equity securities as provided in CBOE Rule 53.6.

†† CBOE will be responsible for any significant differences between its rules and the comparable NASD rule identified.

††† NASD shall not have any Regulatory Responsibilities regarding the CBOE requirement to have Form X–17A–5 filed with CBOE; responsibility for such requirement remains with CBOE.

†††† NASD shall not have any Regulatory Responsibilities regarding the CBOE requirement that the statement have a legend requesting the customer to advise the member of any material change in the customer's investment objectives or financial situation; responsibility for such requirement remains with CBOE.

††††† The NASD Rule requires, among other things, prior written approval of the member employing the associated person in order for such associated person to share in accounts of a customer, whereas the CBOE rule requires consent of the member *carrying* the account. To the extent that the employing member and carrying member are different firms, the NASD's and CBOE's rule differ, and NASD's Regulatory Responsibility will not cover CBOE's rule; responsibility for such requirement remains with CBOE.

†††††† NASD shall not have any Regulatory Responsibilities regarding the CBOE requirement of what must be contained in the complaint file or the timing during which the complaint must be sent to the central file by the branch office; responsibility for such requirement remains with CBOE.

††††††† NASD shall not have any Regulatory Responsibilities regarding the CBOE requirement to disclose on a confirmation whether a transaction was executed on the CBOE; responsibility for such requirement remains with CBOE.

* * * * *

III. Date of Effectiveness of the Proposed Plan and Timing for Commission Action

Pursuant to Section 17(d)(1) of the Act[14] and Rule 17d–2 thereunder,[15] after May 9, 2007, the Commission may, by written notice, declare the plan submitted by CBOE and NASD, File No. 4–536, to be effective if the Commission finds that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among self-regulatory organizations, or to remove impediments to and foster the development of the national market system and a national system for the clearance and settlement of securities transactions and in conformity with the factors set forth in Section 17(d) of the Act.

IV. Solicitation of Comments

In order to assist the Commission in determining whether to approve proposed 17d–2 Plan and to relieve CBOE of the responsibilities which would be assigned to NASD, interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number 4–536 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number 4–536. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan that are filed with the Commission, and all written communications relating to the proposed plan between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the plan also will be available for inspection and copying at the principal offices of the CBOE and NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–536 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7321 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[14] 15 U.S.C. 78q(d)(1).

[15] 17 CFR 240.17d–2.

[16] 17 CFR 200.30–3(a)(34).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55619; File No. SR–Amex–2007–31]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto Relating to Transaction Charges for Equities, ETFs, and Nasdaq UTP Securities

April 12, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2007, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by Amex. On April 10, 2007, the Exchange filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice, as amended, to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise the equities, Exchange Traded Funds and Trust Issued Receipts (''ETFs''), and Nasdaq UTP Fee Schedules to eliminate the five percent discount applied to each firm's total charges for customer orders in equities, ETFs, and Nasdaq UTP securities. The text of the proposed rule change is available on Amex's Web site at *http://www.amex.com,* at Amex, and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange recently revised the transaction charges for its members and member organizations largely relating to the Exchange's new hybrid market trading platform (known as AEMI), the implementation of Regulation NMS, and changes in the competitive landscape for equities and ETFs.[3] These new transaction charges became effective on February 22, 2007. As part of the new transaction charges, the Exchange provided that a five percent discount will be applied to each firm's total charges for customer orders in equities, ETFs, and Nasdaq UTP securities. The five percent discount does not apply to charges for specialists and registered traders. The Exchange is now proposing to eliminate the five percent discount in all product lines. The Exchange will eliminate the five percent discount effective April 1, 2007.

2. Statutory Basis

The proposed fee change is consistent with Section 6(b)(4) of the Act[4] regarding the equitable allocation of reasonable dues, fees, and other charges among exchange members and other persons using exchange facilities.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 55458 (March 13, 2007), 72 FR 13320 (March 21, 2007) (SR–Amex–2007–23).

[4] 15 U.S.C. 78f(b)(4).

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee, or other charge applicable only to a member imposed by Amex, it has become effective pursuant to Section 19(b)(3)(A) of the Act [5] and Rule 19b–4(f)(2) thereunder.[6] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[7]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Amex–2007–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2007–31. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of Amex. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2007–31 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7316 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(2).

[7] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, the Commission considers the period to commence on April 10, 2007, the date on which Amex filed Amendment No. 1. *See* 15 U.S.C. 78s(b)(3)(C).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55616; File No. SR–FICC–2007–03]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change To Clarify the Government Securities Division Rules With Respect to Repo Collateral Substitution Requests

April 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 23, 2007, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by FICC. The Commission is publishing this notice and order to solicit comments from interested parties and to grant accelerated approval of the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to add a final deadline to the repo collateral substitution process of FICC's Government Securities Division (''GSD'').

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Currently, the GSD's rules provide that repo collateral substitution requests for which the notification itself or the information regarding new securities collateral is received after 12:30 p.m. will be processed by the GSD on a good faith basis only.[3] FICC is proposing to impose a final deadline for this process after which FICC will not process a repo collateral substitution until the following business day. This final deadline will be 1 p.m. and will be extended by one hour on days that FICC or the Securities Industry and Financial Markets Association (''SIFMA'') determine are ''high volume'' days. In situations where FICC receives a notification or information regarding the new securities collateral information after the 1 p.m. deadline, the submitting member will be required to resubmit its substitution information on the following business day for processing.[4] FICC will continue to process substitution requests when notification

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by FICC.

[3] All times referred to herein are New York times. This deadline is extended by one hour on ''high volume'' days as described in the GSD's rules.

[4] In situations where FICC receives a notification but not the new securities collateral information before the 1 p.m. deadline, the submitting member will be required to resubmit its substitution information on the following business day for processing.

or new securities collateral information is received between 12:30 p.m. and 1 p.m. on a good faith basis only. In situations where FICC has been notified of a substitution but the new securities collateral has not yet been reported to FICC, FICC will continue to employ the risk management measures that were instituted by FICC in prior rule filings.[5]

FICC believes that imposition of the final deadline will encourage members to submit their repo collateral substitution notification requests and required information on a timely basis and will alleviate the operational burdens associated with late receipt of this information.

The proposed rule change is consistent with Section 17A of the Act,[6] as amended, because it encourages members to submit repo collateral substitution requests and required information associated therewith on a timely basis. As such, it will support the prompt and accurate clearance and settlement of securities transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F)[7] of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. The Commission finds that FICC's proposed rule change is consistent with FICC's obligation under the Act because it encourages FICC's members to submit repo collateral substitution requests and required information associated therewith on a timely basis.[8]

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing in the **Federal Register** because doing so will allow FICC to implement the proposed rule change in April in accordance with its system change implementation schedule.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–FICC–2007–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2007–03. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549. Copies of such filings also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.com/commondocs/rule.filings/rule.filing.07–03.pdf*. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2007–03 and should be submitted on or before May 9, 2007.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–FICC–2007–03) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7322 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

---

[5] Securities Exchange Act Release No. 53534 (March 21, 2006), 71 FR 15781 (March 29, 2006) [File No. SR–FICC–2005–18], as amended by Securities Exchange Act Release No. 55217 (January 31, 2007), 72 FR 5774 (February 7, 2007) [File No. SR–FICC–2006–16].

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55608; File No. SR–NASDAQ–2007–032]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees for Distributors of Certain Market Data From the Nasdaq Market Center

April 10, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. The Exchange has filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to modify Nasdaq Rule 7019(b) to lower the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

distributor fees that are applicable to distributors of Nasdaq TotalView and OpenView data, Nasdaq's full depth of book data feeds for Nasdaq securities and for NYSE and Amex securities.[5] The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *www.nasdaq.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 12, 2007, Nasdaq completed the implementation of the new Nasdaq Market Center Execution System, commonly known as ''Single Book.'' The Single Book is the product of the integration of Nasdaq's three separate execution platforms into a single platform trading all Nasdaq, NYSE, and Amex securities.

A by-product of this integration and the new system is a re-alignment of Nasdaq's data feeds. Under the previous systems, market data for Nasdaq securities was disseminated on one set of data feeds and market data for NYSE and Amex securities was disseminated on another. Because the Single Book processes Nasdaq, NYSE, and Amex securities on a single platform, the market data for all securities is disseminated on a single, unified set of data feeds. For example, full depth of book data for Nasdaq securities was previously disseminated via one feed and full depth data for NYSE and Amex securities was disseminated via another. Starting February 12, 2007, market participants' best bids and offers for all securities are disseminated together via various unified data feeds. Full depth of book data for Nasdaq securities and for NYSE and Amex securities are now also disseminated via a unified full depth of book feed, made available in various formats.

In November 2006, Nasdaq filed SR–NASDAQ–2006–048,[6] a proposed rule change to lower the distributor fees applicable to the full depth feed emanating from the Single Book which has not yet been approved. Therefore, Nasdaq continues to assess its previously-approved fees to its current data feeds. This situation results in economic continuity in that market data recipients will continue to pay the same amount if they continue to receive the same market data elements. Thus, for example, a professional user that receives full depth of book for both Nasdaq and NYSE/Amex stocks in the past paid $70 for the Nasdaq data and $6 for the NYSE/Amex data, and will continue to pay that amount in the future.

Nasdaq continues to assess the currently approved distributor fees for both TotalView and OpenView to recipients of the Single Book depth of book feeds. Currently, pursuant to Rule 7019(b), TotalView and OpenView are each subject to separate monthly distributor fees of $2,500 per month plus either $1,000 per month for internal distributors or $2,500 per month for external distributors. In other words, an external distributor of both TotalView and OpenView would pay $10,000 per month.

Prior to the Single Book, each distributor chose whether it would distribute TotalView, OpenView, or both. Beginning February 12, 2007, the full depth data feeds contained all of the data previously disseminated separately via both TotalView and OpenView. This motivated Nasdaq to propose in SR–NASDAQ–2006–48 a unified fee schedule with a lower distributor fee for TotalView. In the absence of approval of that proposal, beginning April 1, 2007, the first fee-liable billing cycle following the full launch of the Single Book, this will result in higher distributor fees for many vendors because the TotalView and OpenView data elements are included in the unified full depth data feeds, and each set of data continues to be liable for its own separate distributor fee.

In order to avoid this impact, Nasdaq is proposing to lower the current fees until such time as SR–NASDAQ–2006–048 is decided. Due to the variables affecting the level of distributor fees paid by each vendor—whether it distributes TotalView, OpenView, or both and whether it distributes the data internally, externally, or both—it is impossible to replicate exactly the fee schedule proposed for the unified feed. Nasdaq has, however, spent significant time and energy assessing the vendor population and has attempted to lower the fees so as to minimize the aggregate impact on the overall vendor community.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and with Section 6(b)(4) of the Act,[8] in particular, in that lowering the distribution fees for Nasdaq full depth of book feeds for Nasdaq and NYSE and Amex securities will encourage broader dissemination of that data and thereby increase transparency in those securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[11] However, Rule 19b–

[5] The proposed rule change does not alter the Monthly Internal Distributor Fee and the Monthly External Distributor Fee for TotalView.

[6] *See* Securities Exchange Act Release No. 55443 (March 12, 2007), 72 FR 13325 (March 21, 2007).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive the 5-day pre-filing notice

Continued

4(f)(6)(iii)[12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would permit Nasdaq to implement the proposed rule change on April 1, 2007, enabling many vendors to avoid paying higher distributor fees. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[13]

At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–032. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–032 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7317 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

requirement. The Commission has determined to grant this request.

[12] *Id.*

[13] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55609; File No. SR–NASDAQ–2007–033]

Self-Regulatory Organizations; the NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Waive Fees for Distributors of Certain Market Data From the Nasdaq Market Center

April 10, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. The Exchange has filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to modify Nasdaq Rule 7023(c) to waive the distributor fees applicable to Nasdaq OpenView for recipients of the new Nasdaq Level 2 data feed or the new OpenView Basic data feed for a six-month pilot. The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *www.nasdaq.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 12, 2007, Nasdaq completed the implementation of the new Nasdaq Market Center Execution System, commonly known as ''Single Book.'' The Single Book is the product of the integration of Nasdaq's three separate execution platforms into a single platform trading all Nasdaq, NYSE, and Amex securities.

A by-product of this integration and the new system is a re-alignment of Nasdaq's data feeds. Under the previous systems, market data for Nasdaq securities was disseminated on one set of data feeds and market data for NYSE and Amex securities was disseminated on another. Because the Single Book processes Nasdaq, NYSE, and Amex securities on a single platform, the market data for all securities is disseminated via more unified data feeds. For example, previously Nasdaq disseminated each market participant's best bid and offer for Nasdaq securities on the Nasdaq Quotation Dissemination Service (''NQDS'') and for NYSE and Amex securities on the OpenView feed.

Starting February 12, 2007, market participants' best bids and offers for all securities are disseminated via a single data feed, the new Level 2 data feed. Also beginning February 12, 2007, Nasdaq began disseminating OpenView Basic, a new version of its OpenView feed which contains only the best bid and offer from each Nasdaq market participant quoting in NYSE and Amex securities.

Nasdaq is proposing to waive for six months, beginning April 1, 2007 and ending September 30, 2007, the distributor fee for OpenView which would otherwise apply to distributors of the new Level 2 and OpenView Basic data feeds. Waiving the OpenView distributor fees will encourage adoption of the new Level 2 and OpenView Basic data feeds and wider dissemination of that data. In the case of Level 2, the distributor fee waiver is also appropriate because currently there are many more recipients of NQDS data for Nasdaq stocks than for NYSE and Amex stocks and each will become liable for the OpenView distributor fee based upon their receipt and distribution of the Level 2 data feed. Nasdaq believes it is appropriate to provide these new recipients of OpenView data with a reasonable period of time to become familiar with the new OpenView data.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Section 6(b)(4) of the Act,[6] in particular, in that waiving the OpenView distribution fee for distributors that receive NASDAQ market data for NYSE and Amex securities via Level 2 or OpenView Basic will encourage broader dissemination of that data and thereby increase transparency in those securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [7] and Rule 19b–4(f)(6) thereunder.[8]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[9] However, Rule 19b–4(f)(6)(iii) [10] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would permit Nasdaq to implement the waiver of the distributor fee for OpenView on April 1, 2007, for a six-month period. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[11]

At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement. The Commission has determined to grant this request.

[10] *Id.*

[11] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–033 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–033. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–033 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7318 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55610; File No. SR–NASDAQ–2007–034]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Augment the TotalView Enterprise License

April 10, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. The Exchange has filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to add Nasdaq OpenView, which contains full depth of book data for Nasdaq trading of NYSE and Amex stocks, to the TotalView Enterprise License set forth in Nasdaq Rule 7023(a). The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *www.nasdaq.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 12, 2007, Nasdaq completed the implementation of the new Nasdaq Market Center Execution System, commonly known as ''Single Book.'' The Single Book is the product of the integration of Nasdaq's three separate execution platforms into a single platform trading all Nasdaq, NYSE, and Amex securities.

A by-product of this integration and the new system is a re-alignment of Nasdaq data feeds. Under the previous systems, market data for Nasdaq securities was disseminated on one set of data feeds and market data for NYSE and Amex securities was disseminated on another. Because the Single Book processes Nasdaq, NYSE, and Amex securities on a single platform, the market data for all securities is disseminated on a single set of data feeds. For example, full depth of book data for Nasdaq securities was previously disseminated via one feed and full depth data for NYSE and Amex securities was disseminated via another. Starting February 12, 2007, market participants' best bids and offers for all securities are disseminated together via various unified data feeds. Full depth of book data for Nasdaq securities and for NYSE and Amex securities are now also disseminated via a unified full depth of book feed, made available in various formats.

Nasdaq has not received regulatory approval for the fee schedule for its new unified system and data feeds. In November 2006, Nasdaq filed SR–NASDAQ–2006–048,[5] a proposed rule change to lower the distributor fees applicable to the full depth feed emanating from the Single Book which has not yet been approved. Therefore, Nasdaq must continue to assess its previously-approved fees to its new data feeds. This situation results in economic continuity in that market data recipients will continue to pay the same amount if they continue to receive the same market data elements. Thus, for example, a professional user that receives full depth of book for both Nasdaq and NYSE/Amex stocks in the past paid $70 for the Nasdaq data and $6 for the NYSE/Amex data, and will continue to pay that amount in the future.

With respect to purchasers of the TotalView Enterprise License, however, Nasdaq's inability to gain approval of its unified fee schedule will cause economic harm. Nasdaq had intended that purchasers of the TotalView Enterprise License would, upon the launch of the Single Book on February 12, 2007, have gained the ability to distribute the unified TotalView feed containing full depth of book for Nasdaq, NYSE, and Amex securities. Because Nasdaq has not received final approval of the unified feeds and fee schedule, it is unclear that the Enterprise License includes the ability to distribute market data for NYSE and Amex stocks.

Accordingly, Nasdaq is proposing to add the current OpenView feed to the Enterprise License, thereby clearly establishing that purchasers of the Enterprise License have the ability to distribute full depth of book for Nasdaq, NYSE, and Amex securities for the same currently approved fee. This will be a benefit to purchasers of the Enterprise License in that they will be permitted to distribute more data for the same fee.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[6] in general, and with Section 6(b)(4) of the Act,[7] in particular, in that adding OpenView to the TotalView Enterprise License will encourage broader dissemination of that data and thereby increase transparency in those securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate, it has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 55443 (March 12, 2007), 72 FR 13325 (March 21, 2007).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[10] However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would permit Nasdaq to implement the proposed rule change on April 1, 2007, clarifying that the Enterprise License includes the ability to distribute market data for NYSE and Amex securities. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[12]

At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–034 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–034. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–034 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7319 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement. The Commission has determined to grant this request.

[11] *Id.*

[12] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55611; File No. SR–NASDAQ–2007–035]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Create a Pilot Non-Professional Fee for Certain Market Data From the Nasdaq Market Center

April 10, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2007, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by Nasdaq. The Exchange has filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to establish for a twelve-month pilot period a $1 per month fee for non-professional use of real-time quotation information from the Nasdaq Market Center trading of NYSE and Amex listed stocks. The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *www.nasdaq.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

To encourage more competition in the trading and quoting of NYSE and Amex listed stocks, as well as to encourage subscribership to Nasdaq full-depth products, Nasdaq is proposing Rule 7023(c)(2) to establish a $1 per month fee for non-professional subscribers to OpenView, which consists of real-time market participant quotation information regarding Nasdaq's trading of NYSE and Amex listed stocks, currently priced at $6 per month for all subscribers—professional or non-professional. The aggregate best bid and offer is one data element within Nasdaq OpenView, and is available for distribution free of charge. Nasdaq believes that this will promote wider distribution of data and benefit investors wishing to use that data in making investment decisions.

The establishment of non-professional fees is a well-established practice of the network processors that distribute real-time consolidated data for Nasdaq, NYSE, and Amex stocks. It has also been an approved practice of the Nasdaq with respect to proprietary products, including the Nasdaq Quotation Dissemination Service. As such, Nasdaq believes that non-professional fees have been determined to be consistent with the Act and also to be in the best interests of investors and the public.

Nasdaq is proposing to establish the non-professional fee for OpenView as a twelve-month pilot to determine whether the proposed fee will in fact spur competition and increase transparency, as non-professional fees have done in the past.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Section 6(b)(4) of the Act,[6] in particular, in that establishment of a $1 per month non-professional fee for OpenView will encourage broader dissemination of that data and thereby increase transparency in those securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8]

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[9] However, Rule 19b–4(f)(6)(iii)[10] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would permit Nasdaq to implement the one-year pilot on April 1, 2007, lowering the charge for the receipt of OpenView by non-professionals from $6 per month to $1 per month, which should expand the distribution of the information. For this reason, the Commission designates the proposed rule change to be operative upon filing with the Commission.[11]

At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–035 on the subject line.

Paper comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–035. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–035 and should be submitted on or before May 9, 2007.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement. The Commission has determined to grant this request.

[10] *Id.*

[11] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7320 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55620; File No. SR–NASDAQ–2007–039]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Modify the Distributor Fee for Nasdaq Index Weighting Information

April 12, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 4, 2007, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to modify distributor fees for Nasdaq Index Weighting Information. The text of the proposed rule change is available at Nasdaq, the Commission's Public Reference Room, and *www.nasdaq.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to modify distributor fees for Nasdaq Index Weighting Information.

Nasdaq disseminates Nasdaq Index Weighting data via the Nasdaq Index Dissemination Service (''NIDS'') data feed and via the Nasdaq Trader Web site. Nasdaq Index Weighting reports include component and weighting information for a number of Nasdaq indices on a daily basis. Market participants pay a fee to obtain a license to distribute the Index Weighting Information to end users. The fees are based on the number of end users (whether internal or external to the organization) and the frequency of the distribution. The fees permitting distribution with unlimited frequency range from $1000 for the right to distribute the data to 1–500 subscribers up to $5,000 for the right to distribute to 10,000+ subscribers. The fees permitting distribution of data once a month, quarter, or year range from $500 for the right to distribute data to 1–500 subscribers to $1,000 for the right to distribute to 10,000+ subscribers.

The proposed rule change would decrease the distributor fee for the lowest pricing tier, 1–500 subscribers, from $1,000 to $300 in the case of unlimited frequency of distribution, and from $500 to $275 in the case of distribution once a month, quarter, or year. Although the fee schedules provide for multiple tiered pricing based on the number of end users, the lowest pricing tier is the most common option selected by existing customers. The proposed fee would apply to distributors receiving the data via any delivery platform, including via NIDS or the Nasdaq Trader Web site. Distributors receiving the data via more than one delivery platform would be charged only once. The remaining tiers of the fee schedules (*i.e.*, fees for 501–999, 1,000–4,999, 5,000–9,999, and 10,000+ subscribers) will not change under this proposal.

Nasdaq believes that the fee decrease would make this data report more attractive to vendors who may already be receiving and distributing other Nasdaq data feeds, thereby promoting the broader dissemination of Index Weighting Information.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(4) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which the Nasdaq operates or controls, and it does not unfairly discriminate between customers, issuers, brokers, or dealers. The proposed rule change reflects demand patterns for Index Weighting Information and is designed to provide an equitable allocation of fees across the customer base of Nasdaq market data distributors. Nasdaq further believes that this rule change would encourage the broader distribution of the Index Weighting data, thus improving transparency and thereby benefiting the investing public.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which Nasdaq consents, the Commission will:

(A) by order approve such proposed rule change; or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2007–039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–039. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NASDAQ–2007–039 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7330 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[5] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55618; File No. SR–NYSE–2007–32]

Self-Regulatory Organizations; New York Stock Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, and Amendment No. 1 Thereto, Relating to Rule 15B(T) (Protected Bids and Offers of Away Markets)

April 11, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 22, 2007, the New York Stock Exchange, LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the NYSE. The Exchange filed the proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. On April 9, 2007, the Exchange filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to rescind NYSE Rule 15B(T), a temporary rule which describes the obligations of Exchange member organizations when sending Intermarket Sweep Orders (''ISOs'') to the Exchange prior to March 5, 2007, the Trading Phase Date of Regulation NMS under the Act[5] (''Reg NMS''). The text of the proposed rule change is available at the Exchange, on the Exchange's Web site at *http://www.nyse.com*, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 26, 2007, the Exchange adopted NYSE Rule 15B(T),[6] which requires member organizations that send ISOs to the Exchange prior to March 5, 2007, the Trading Phase Date of Reg. NMS, to simultaneously send an ISO (or comparable order) for the full displayed size of the top of the book of every other ITS participant displaying a better-priced protected quotation.[7]

Given that ISO requirements are contained in NYSE Rule 13 now that the Trading Phase Date has passed, the Exchange, through this filing, seeks to delete NYSE Rule 15B(T) from Exchange Rules in order to eliminate potential confusion regarding the procedures for member organizations when sending ISOs to the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirement under Section 6(b)(5) of the Act[8] that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 242.600 *et seq.*

[6] *See* Securities Exchange Act Release No. 55210 (January 31, 2007), 72 FR 5777 (February 7, 2007) (SR–NYSE–2007–08).

[7] *See* telephone conversation between Craig Hammond, Managing Director, Office of General Counsel, NYSE, and Christopher W. Chow, Special Counsel, Division of Market Regulation Commission, on April 11, 2007.

[8] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the forgoing rule change does not: (1) Significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

NYSE has asked that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) under the Act.[11] The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the immediate removal of the temporary rule should eliminate potential confusion relating to the usage of ISOs on the Exchange. For this reason, the Commission designates the proposed rule change to be effective and operative upon filing with the Commission.[12]

At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.[13]

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii). Rule 19b–4(f)(6) also requires that the self-regulatory organization to give the Commission notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission grants the Exchange's request for a waiver of the five-day pre-filing requirement.

[12] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C), the Commission considers the period to commence on April 9, 2007, the date NYSE filed Amendment No. 1 to the proposed rule change.

IV. Solicitation of Comments

nterested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2007–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2007–32. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2007–32 and should be submitted on or before May 9, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–7323 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–55621; File No. SR–NYSEArca–2006–86]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change and Amendments No. 1, 2, 3, and 4 Thereto and Order Granting Accelerated Approval of the Proposed Rule Change as Modified by Amendments No. 2 and 4 Thereto Adopting Generic Listing Standards for Exchange-Traded Funds Based on International or Global Indexes or Indexes Described in Exchange Rules Previously Approved by the Commission as Underlying Benchmarks for Derivative Securities

April 12, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 13, 2006, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. On March 19, 2007, the Exchange filed Amendment No. 1 to the proposal. On March 20, 2007, the Exchange filed Amendment No. 2 to the proposal.[3] On April 4, 2007, the Exchange filed Amendment No. 3 to the filing. On April 10, 2007, the Exchange filed Amendment No. 4 to the filing.[4] This order provides notice of the proposal, as amended, and approves the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NYSE Arca, through its wholly owned subsidiary NYSE Arca Equities, Inc. (''NYSE Arca Equities''), proposes to amend its rules governing NYSE Arca, L.L.C. (also referred to as the ''NYSE Arca Marketplace''), the equities trading facility of NYSE Arca Equities. The Exchange proposes to amend NYSE Arca Equities Rules 5.2(j)(3), 5.5(g)(2), and 8.100 to include generic listing standards for Investment Company

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 2 replaced and superseded the original filing and Amendment No. 1 in their entirety.

[4] Amendment No. 4 superseded Amendment No. 3 in its entirety. In Amendment No. 4, the Exchange made clarifying changes to Exhibit 5 and the purpose section, including reflecting a recent approval of an exchange rule that changed the current rule text.

Units (''Units'') and Portfolio Depositary Receipts (''PDRs'') (''Units'' and ''PDRs'' together referred to herein as ''exchange-traded funds'' or ''ETFs'') that are based on international or global indexes or on indexes described in exchange rules that have been previously approved by the Commission for the trading of ETFs and other index-based securities. The text of the proposed rule change is available at the Exchange, from the Commission's Public Reference Room, and on NYSE Arca's Web site (*www.nysearca.com*).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rules 5.2(j)(3), 5.5(g)(2), and 8.100 to include generic listing standards for series of Units and PDRs that are based on international or global indexes or on indexes described in rules previously approved by the Commission under Section 19(b)(2) of the Exchange Act [5] for the trading of ETFs, options, or other specified index-based securities. This proposal would enable the Exchange to list and trade ETFs pursuant to Rule 19b–4(e) under the Exchange Act [6] if each of the conditions set forth in Commentary .01 to NYSE Arca Equities Rule 5.2(j)(3) or Commentary .01 to NYSE Arca Equities Rule 8.100 is satisfied. Rule 19b–4(e) provides that the listing and trading of a new derivative securities product by a self-regulatory organization (''SRO'') shall not be deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b–4, if the Commission has approved, pursuant to Section 19(b) of the Exchange Act, the SRO's trading rules, procedures, and listing standards for the product class that would include the new derivatives securities product, and the SRO has a surveillance program for the product class.[7] Similar proposals for the New York Stock Exchange LLC (''NYSE''), The NASDAQ Stock Market LLC (''Nasdaq''), and the American Stock Exchange LLC (''Amex'') have been approved by the Commission.[8]

Exchange-Traded Funds

NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) provide standards for initial and continued listing of Units, which are securities representing interests in a registered investment company that could be organized as a unit investment trust, an open-end management investment company, or a similar entity. The investment company must hold securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities, or the investment company must hold securities in another registered investment company that holds securities in such a manner.[9] NYSE Arca Equities Rule 8.100 allows for the listing and trading on the Exchange of PDRs. PDRs represent securities based on a unit investment trust that holds the securities that comprise an index or portfolio underlying a series of PDRs. Pursuant to NYSE Arca Equities Rules 5.2(j)(3) and 8.100, Units and PDRs must be issued in a specified aggregate minimum number in return for a deposit of specified securities and/or a cash amount. When aggregated in the same specified minimum number, Units and PDRs must be redeemable by the issuer for the underlying securities and/or cash.

To meet the objective of providing investment returns that correspond to the price, dividend, and yield performance of the underlying index, an ETF may use a ''replication'' strategy or a ''representative sampling'' strategy with respect to the ETF portfolio.[10] An ETF using a replication strategy invests in each stock of the underlying index in about the same proportion as that stock is represented in the index itself. An ETF using a representative sampling strategy generally invests in a significant number but not all of the component securities of its underlying index, and will hold stocks that, in the aggregate, are intended to approximate the full index in terms of key characteristics, such as price/earnings ratio, earnings growth, and dividend yield.

In addition, an ETF portfolio may be adjusted in accordance with changes in the composition of the underlying index or to maintain compliance with requirements applicable to a regulated investment company under the Internal Revenue Code (''IRC'').[11]

Generic Listing Standards for Exchange-Traded Funds

The Commission has previously approved generic listing standards for ETFs based on indexes that consist of stocks listed on U.S. exchanges.[12] In general, the proposed criteria for the underlying component securities in the international and global indexes are similar to those for the domestic indexes, but with modifications as appropriate for the issues and risks associated with non-U.S. securities.

In addition, the Commission has previously approved rules governing the listing and trading of ETFs based on international indexes—those based on non-U.S. component stocks—as well as global indexes—those based on non-U.S. and U.S. component stocks.[13]

The Commission has also approved rules of other exchanges that permit the listing pursuant to Rule 19b–4(e) of index-based derivatives where the Commission had previously approved rules contemplating the trading of

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 240.19b–4(e).

[7] When relying on Rule 19b–4(e), the SRO must submit Form 19b–4(e) to the Commission within five business days after the exchange begins trading a new derivative securities product. *See* 17 CFR 240.19b–4(e)(2)(ii). *See also* Securities Exchange Act Release No. 40761 (December 8, 1998), 63 FR 70952 (December 22, 1998).

[8] *See* Securities Exchange Act Release No. 55269 (February 9, 2007), 72 FR 7490 (February 15, 2007) (SR–Nasdaq–2006–050); Securities Exchange Act Release No. 55113 (January 18, 2007), 72 FR 3179 (January 24, 2007) (SR–NYSE–2006–101); Securities Exchange Act Release No. 54739 (November 9, 2006), 71 FR 66993 (November 17, 2006) (SR–Amex–2006–78); and Securities Exchange Act Release No. 55018 (December 28, 2006), 72 FR 1040 (January 9, 2007) (SR–Amex–2006–109) (making clarifying changes to the generic listing standards set forth in SR–Amex–2006–78).

[9] *See* NYSE Arca Equities Rule 5.2(j)(3)(A)(i)(a)–(b).

[10] In either case, an ETF, by its terms, may be considered invested in the securities of the underlying index to the extent the ETF invests in sponsored American Depositary Receipts (''ADRs''), Global Depositary Receipts (''GDRs''), or European Depositary Receipts (''EDRs'') that trade on exchanges with last-sale reporting of securities in the underlying index.

[11] For an ETF to qualify for tax treatment as a regulated investment company, it must meet several requirements under the IRC, including requirements with respect to the nature and the value of the ETF's assets.

[12] *See* Commentary .01 to NYSE Arca Equities Rule 5.2(j)(3); Commentary .01 to NYSE Arca Equities Rule 8.100; Securities Exchange Act Release No. 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14) (approving generic listing standards for Units and PDRs).

[13] *See, e.g.*, Securities Exchange Act Release No. 53999 (June 15, 2006), 71 FR 35981 (June 22, 2006) (SR–NYSEArca–2006–30) (approving the trading of certain Wisdom Trade exchange-traded funds); and Securities Exchange Act Release No. 53230 (February 6, 2006), 71 FR 7594 (February 13, 2006) (SR–PCX–2005–116) (approving the listing and trading of funds of iShares, Inc. based on certain MSCI country-specific indexes).

specified index-based derivatives on the same index, on the condition that all of the standards set forth in those orders, in particular with respect to surveillance sharing agreements, continued to be satisfied.[14]

The Exchange believes that adopting additional generic listing standards for ETFs and applying Rule 19b–4(e) thereto should fulfill the intended objective of that rule by allowing those ETFs that satisfy the proposed generic listing standards to commence trading without the need for the public comment period and Commission approval. The proposed rules have the potential to reduce the time frame for bringing ETFs to market, thereby reducing the burdens on issuers and other market participants. The failure of a particular ETF to comply with the proposed generic listing standards under Rule 19b–4(e) would not, however, preclude the Exchange from submitting a separate filing pursuant to Section 19(b)(2) requesting Commission approval to list and trade a particular ETF.

Requirements for Listing and Trading ETFs Based on International and Global Indexes or Previously Approved Indexes

ETFs listed pursuant to these proposed generic listing standards for international and global indexes, and for indexes described in rules previously approved by the Commission for trading of options or other derivative securities, would be traded, in all other respects, under the Exchange's existing trading rules and procedures that apply to ETFs[15] and would be covered under the Exchange's surveillance program for derivative products. The Exchange represents that its surveillance procedures are adequate to properly monitor the trading of Units and PDRs listed pursuant to the proposed new listing standards and those traded pursuant to UTP. Specifically, the Exchange will rely on its existing surveillance procedures governing derivative products, which apply both to Exchange-listed Units and PDRs and those traded pursuant to UTP. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

To list an ETF pursuant to the proposed generic listing standards for international or global indexes, and for indexes described in exchange rules previously approved by the Commission for trading of options or other derivative securities, the index underlying the Units or PDRs must satisfy all the conditions contained in proposed Commentary .01 to NYSE Arca Equities Rule 5.2(j)(3) (for Units) or proposed Commentary .01 to NYSE Arca Equities Rule 8.100 (for PDRs). However, for Units or PDRs traded on the Exchange pursuant to UTP, only the provisions of paragraphs (c), (e), (f), (g), and (h) of Commentary .01 to NYSE Arca Equities Rule 5.2(j) and NYSE Arca Equities Rule 8.100(c) and paragraphs (c), (e), (f), and (g) of Commentary .01 to NYSE Arca Equities Rule 8.100 would apply. These paragraphs relate to trading increments, trading hours, dissemination of IIV, implementation of surveillance procedures, information circulars, and prospectus delivery.

As with the existing generic standards for ETFs based on domestic indexes, these generic listing standards are intended to ensure that stocks with substantial market capitalization and trading volume account for a substantial portion of the weight of an index or portfolio. While the standards in this proposal are based on the standards contained in the current generic listing standards for ETFs based on domestic indexes, they have been adapted as appropriate to apply to international and global indexes.

As proposed, the definition section of each of NYSE Arca Equities Rules 5.2(j)(3) and 8.100 would be revised to include definitions of U.S. Component Stock and Non-U.S. Component Stock. These new definitions would provide the basis for the standards for indexes with either domestic or international stocks, or a combination of both. A ''Non-U.S. Component Stock'' would mean an equity security that is not registered under Section 12(b) or 12(g) of the Exchange Act,[16] and that is issued by an entity that (1) is not organized, domiciled, or incorporated in the United States, and (2) is an operating company (including a real estate investment trust) or income trust, but excluding an investment trust, unit trust, mutual fund, or derivative). This definition is designed to create a category of component stocks that are issued by companies that are not based in the United States, but that also are not subject to oversight through Commission registration, and would include sponsored GDRs and EDRs. This definition would appear in an amended introductory paragraph in NYSE Arca Equities Rule 5.2(j)(3) and new subsection (4) of NYSE Arca Equities Rule 8.100(a).

A ''U.S. Component Stock'' would mean an equity security that is registered under Section 12(b) or 12(g) of the Exchange Act or an ADR, the underlying equity security of which is registered under Section 12(b) or 12(g) of the Exchange Act. An ADR with an underlying equity security that is registered pursuant to the Exchange Act is considered a U.S. Component Stock because the issuer of that underlying security is subject to Commission jurisdiction and must comply with Commission rules. This definition would appear in an amended introductory paragraph in NYSE Arca Equities Rule 5.2(j)(3) and new subsection (3) of NYSE Arca Equities Rule 8.100(a).

The Exchange proposes that, to list a Unit or PDR based on an international or global index or portfolio pursuant to the generic listing standards, such index or portfolio must meet the following criteria:

- Component stocks that in the aggregate account for at least 90% of the weight of the index or portfolio each shall have a minimum market value of at least $100 million (proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(a)(B)(1), and 8.100, Commentary .01(a)(B)(1));
- Component stocks that in the aggregate account for at least 90% of the weight of the index or portfolio each shall have a minimum worldwide monthly trading volume during each of the last six months of at least 250,000 shares (proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(a)(B)(2) and 8.100, Commentary .01(a)(B)(2));
- The most heavily weighted component stock may not exceed 25% of the weight of the index or portfolio and the five most heavily weighted component stocks may not exceed 60% of the weight of the index or portfolio (proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(a)(B)(3) and 8.100, Commentary .01(a)(B)(3));
- The index or portfolio shall include a minimum of 20 component stocks (proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(a)(B)(4) and 8.100, Commentary .01(a)(B)(4)); and
- Each U.S. Component Stock in the index or portfolio shall be listed on a national securities exchange and shall be an NMS Stock as defined in Rule 600 of Regulation NMS under the Exchange Act, and each Non-U.S. Component Stock in the index or portfolio shall be listed on an exchange that has last-sale reporting (proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(a)(B)(5) and 8.100, Commentary .01(a)(B)(5)).

[14] *See* NYSE Arca Equities Rule 5.2(j)(6); Securities Exchange Act Release No. 52204 (August 3, 2005), 70 FR 46559 (August 10, 2005) (SR–PCX–2005–63) (approving generic listing standards for index-linked securities).

[15] *See* NYSE Arca Equities Rules 5.2(j)(3), 5.5(g)(2), and 8.100.

[16] 15 U.S.C. 78*l*(b) or (g).

The Exchange believes that these proposed standards are reasonable for international and global indexes, and, when applied in conjunction with the other listing requirements, would result in the listing and trading on the Exchange of ETFs that are sufficiently broad-based in scope and not readily susceptible to manipulation. The Exchange also believes that the proposed standards would result in ETFs that are adequately diversified in weighting for any single security or small group of securities, which should significantly reduce concerns that trading in an ETF based on an international or global index could become a surrogate for the trading of securities not registered in the United States.

The Exchange further notes that, while these standards are similar to those for indexes that include only U.S. Component Stocks, they differ in certain important respects and are generally more restrictive, reflecting greater concerns over portfolio diversification with respect to ETFs investing in components that are not individually registered with the Commission. First, in the proposed standards, component stocks that in the aggregate account for at least 90% of the weight of the index or portfolio each shall have a minimum market value of at least $100 million, compared to a minimum market value of at least $75 million for indexes with only U.S. Component Stocks.[17] Second, in the proposed standards, the most heavily weighted component stock may not exceed 25% of the weight of the index or portfolio, in contrast to a 30% standard for an index or portfolio comprised of only U.S. Component Stocks (in the case of Units, but not PDRs, which has a 25% standard). Third, in the proposed standards, the five most heavily weighted component stocks may not exceed 60% of the weight of the index or portfolio, compared to a 65% standard for indexes comprised of only U.S. Component Stocks. Fourth, the minimum number of component stocks in the proposed standards is 20, in contrast to a minimum of 13 in the standards for an index or portfolio with only U.S. Component Stocks. Finally, the proposed standards require that each Non-U.S. Component Stock included in the index or portfolio be listed and traded on an exchange that has last-sale reporting.

The Exchange also proposes to modify Commentary .01(b)(2) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(b)(3) to NYSE Arca Equities Rule 8.100 to require that the index value for an ETF listed pursuant to the proposed standards for international and global indexes be widely disseminated by one or more major market data vendors at least every 60 seconds during the time when the ETF shares trade on the NYSE Arca Marketplace. In contrast, the index value for an ETF listed pursuant to the existing standards for domestic indexes must be disseminated at least every 15 seconds during the trading day. This 60-second standard reflects limitations, in some instances, on the frequency of intra-day trading information with respect to Non-U.S. Component Stocks and that in many cases, trading hours for overseas markets overlap only in part, or not at all, with NYSE Arca Marketplace trading hours.

In addition, Commentary .01(c) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(c) to NYSE Arca Equities Rule 8.100 are being modified to define the term ''Intraday Indicative Value'' (''IIV'') as the estimate, updated at least every 15 seconds, during the Core Trading Session (9:30 a.m. to 4 p.m., Eastern Time), and, if applicable the Opening Session (4 a.m. to 9:30 a.m., Eastern Time) of the value of a share of each ETF, for ease of reference in these rules and also in NYSE Arca Equities Rules 5.5(g)(2)(b) and 8.100(e)(2)(ii) regarding continued listing standards. The Exchange also proposes to clarify in Commentary .01(c) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(c) to NYSE Arca Equities Rule 8.100 that the IIV would be updated at least every 15 seconds during regular market hours and during any pre-market trading sessions for the ETF to reflect changes in the exchange rate between the U.S. dollar and the currency in which any component stock is denominated. In addition, if the IIV does not change during some or all of the period when trading is occurring on the Exchange, then the last official calculated IIV must remain available throughout Exchange trading hours.

The Exchange is proposing that it may designate a series of Units or PDRs for trading during the Opening Session or Late Trading Session (4 p.m. to 8 p.m., Eastern Time) as long as the index value and IIV dissemination requirements of Commentary .01(b)(2) and (c) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(b)(3) and (c) to NYSE Arca Equities Rule 8.100 are met. If there is no overlap with the trading hours of the primary market trading the underlying components of a series of Units or PDRs, the Exchange may designate such series for trading in the Opening Session as long as the last official calculated IIV remains available. Although the IIV does not need to be calculated during the Exchange's Late Trading Session, the last official calculated IIV must also remain available during such session.

The Exchange is also proposing to add a subsection (i) to Commentary .01 to NYSE Arca Equities Rule 5.2(j)(3) and a subsection (h) to Commentary .01 to NYSE Arca Equities Rule 8.100 regarding the creation and redemption process for ETFs and compliance with Federal securities laws for ETFs listed pursuant to the new generic listing standards. These new subsections would apply to Units listed pursuant to Commentary .01(a)(B) or (C) to NYSE Arca Equities Rule 5.2(j)(3) and for PDRs listed pursuant to Commentary .01(a)(B) or (C) to NYSE Arca Equities Rule 8.100. They would require that the statutory prospectus or the application for exemption from provisions of the Investment Company Act of 1940 for the ETF being listed pursuant to these new standards must state that the ETF must comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with redemption securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933.

The Commission has approved generic standards providing for the listing pursuant to Rule 19b–4(e) of other derivative products based on indexes described in rules previously approved by the Commission under Section 19(b)(2) of the Exchange Act.[18] The Exchange proposes to include in the generic standards for the listing of Units and PDRs, in new Commentary .01(a)(C) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(a)(C) to NYSE Arca Equities Rule 8.100, indexes described in rule changes that have been approved by the Commission in connection with the trading of options, PDRs, Units, Index-Linked Exchangeable Notes, or Index-Linked Securities. The Exchange believes that the application of that standard to ETFs is appropriate because the underlying index would have been subject to Commission review in the context of the approval of rules contemplating the trading of other derivatives. This new generic standard would be limited to stock indexes and portfolios and would require that each component stock be either: (1) A U.S. Component Stock that

[17] Market value is calculated by multiplying the total shares outstanding by the price per share of the component stock.

[18] *See supra* note 12.

is listed on a national securities exchange and is an NMS Stock as defined in Rule 600 of Regulation NMS under the Exchange Act; or (2) a Non-U.S. Component Stock that is listed and traded on an exchange that has last-sale reporting.

The Exchange proposes to modify the initial and continued listing standards relating to disseminated information relating to ETFs to formalize in the rules existing best practices for providing equal access to material information about the value of ETFs. Pursuant to NYSE Arca Equities Rules 5.2(j)(3)(A)(v) and NYSE Arca Equities 8.100(e)(1)(ii), prior to approving an ETF for listing, the Exchange would obtain a representation from the ETF issuer that the net asset value (''NAV'') per share would be calculated daily and made available to all market participants at the same time. Proposed NYSE Arca Equities Rules 5.5(g)(2)(b) and 8.100(e)(2)(ii) would set forth the trading halt parameters for ETFs. In particular, the proposed rules specifically provide that, if the IIV (as defined in Commentary .01 to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01 to NYSE Arca Equities Rule 8.100) or the index value applicable to that series of ETFs is not being disseminated as required when the Exchange is the listing market, the Exchange may halt trading during the day in which the interruption to the dissemination of the IIV or the index value occurs. If the interruption to the dissemination of the IIV or the index value persists past the trading day in which it occurred, the Exchange would halt trading no later than the beginning of the trading day following the interruption.

In addition, proposed NYSE Arca Equities Rules 5.5(g)(2)(b) and 8.100(e)(2)(ii) have been modified to provide that the Exchange: (1) Would halt trading in a series of ETFs if the circuit breaker parameters of Rule 7.12 have been reached; and (2) in exercising its discretion to halt trading in a series of ETFs, would consider factors such as the extent to which trading in the underlying securities is not occurring or whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present, in addition to other relevant factors.

The Exchange is proposing other minor and clarifying changes to NYSE Arca Equities Rules 5.2(j)(3) and 8.100. The standards set forth in Commentary .01(a)(A) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(a)(A) to NYSE Arca Equities Rule 8.100 are being modified to make the wording of each requirement consistent. In addition, Commentary .01(a)(A)(5) to each of NYSE Arca Equities Rules 5.2(j)(3) and 8.100 would be modified to reflect the adoption of Regulation NMS. Proposed Commentary .01(b)(4) to NYSE Arca Equities Rule 5.2(j)(3) and Commentary .01(b)(4) to NYSE Arca Equities Rule 8.100 would be added to make sure that an entity that advises index providers or calculators has in place procedures designed to prevent the use and dissemination of material non-public information regarding the index underlying the ETF.

The Exchange is also proposing the following clean-up changes to NYSE Arca Equities Rule 8.100 in order to make it consistent with NYSE Arca Equities Rule 5.2(j)(3). The Exchange proposes changing the term ''Reporting Authority'' to ''one or more major market data vendors'' in Commentary .01(c) to NYSE Arca Equities Rule 8.100.[19] Also, Commentary .01(c) to NYSE Arca Equities Rules 5.2(j)(3) and 8.100 would be modified to clarify that the obligation to disseminate an IIV applies to Units and PDRs that are listed or traded on the Exchange (which would include Units or PDRs traded pursuant to UTP).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[20] in general, and furthers the objectives of Section 6(b)(5),[21] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2006–86 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2006–86. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of NYSE Arca. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2006–86 and should be submitted on or before May 9, 2007.

[19] *See* Securities Exchange Act Release No. 52809 (November 18, 2005), 70 FR 71590 (November 29, 2005) (SR–PCX–2005–108) (approving change to listing standards for Units to allow ''one or more major market data vendors'' to satisfy dissemination requirements rather than ''Reporting Authority'').

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[22] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Exchange Act[23] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Currently, the Exchange must file a proposed rule change with the Commission pursuant to Section 19(b)(1) of the Exchange Act[24] and Rule 19b–4 thereunder[25] to list and trade any ETF based on an index comprised of foreign securities. The Exchange also must file a proposed rule change to list and trade ETFs based on indexes or portfolios described in rule changes that have previously been approved by the Commission as underlying benchmarks for derivative securities. However, Rule 19b–4(e) provides that the listing and trading of a new derivative securities product by an SRO will not be deemed a proposed rule change pursuant to Rule 19b–4(c)(1) if the Commission has approved, pursuant to Section 19(b) of the Exchange Act, the SRO's trading rules, procedures, and listing standards for the product class that would include the new derivative securities product, and the SRO has a surveillance program for the product class. The Exchange's proposed rules for the listing and trading of ETFs pursuant to Rule 19b–4(e) based on (1) certain indexes with components that include foreign securities or (2) indexes or portfolios previously described in exchange rules that have been approved by the Commission as underlying benchmarks for derivative securities, fulfill these requirements. Use of Rule 19b–4(e) by NYSE Arca to list and trade such ETFs should promote competition, reduce burdens on issuers and other market participants, and make such ETFs available to investors more quickly.[26]

The Commission previously has approved generic listing standards for other exchanges that are substantially similar to those proposed here by NYSE Arca.[27] This proposal does not appear to raise any novel regulatory issues. Therefore, the Commission finds that NYSE Arca's proposal is consistent with the Exchange Act on the same basis that it approved the other exchanges' generic listing standards for ETFs based on international or global indexes or on indexes or portfolios described in exchange rules that have been previously approved by the Commission as underlying benchmarks for derivative securities.

Proposed Commentary .01(a)(A) and (B) to NYSE Arca Equities Rules 5.2(j)(3) and 8.100 establish standards for the composition of an index or portfolio underlying an ETF. These requirements are designed, among other things, to require that components of an index or portfolio underlying the ETF are adequately capitalized and sufficiently liquid, and that no one security dominates the index. The Commission believes that, taken together, these standards are reasonably designed to ensure that securities with substantial market capitalization and trading volume account for a substantial portion of any underlying index or portfolio, and that when applied in conjunction with the other applicable listing requirements, will permit the listing and trading only of ETFs that are sufficiently broad-based in scope to minimize potential manipulation. The Commission further believes that the proposed listing standards are reasonably designed to preclude NYSE Arca from listing and trading ETFs that might be used as surrogate for trading in unregistered securities. The requirement that each component security underlying an ETF be an NMS Stock (in the case of a U.S. Component Stock) or listed on an exchange and subject to last-sale reporting (in the case of a Non-U.S. Component Stock) also should contribute to the transparency of the market for these ETFs.

The proposed generic listing standards will permit NYSE Arca to list and trade an ETF if the Commission has previously approved an SRO rule change that contemplates listing and trading a derivative product based on the same underlying index. NYSE Arca would be able to rely on that earlier approval order, provided that: (1) The securities comprising the underlying index consist of U.S. Component Stocks or Non-U.S. Component Stocks, as set forth in proposed NYSE Arca Equities Rules 5.2(j)(3), 8.100(a)(3), and 8.100(a)(4); and (2) NYSE Arca complies with the commitments undertaken by the other SRO set forth in the prior order, including any surveillance-sharing arrangements with a foreign market.

The Commission believes that NYSE Arca's proposal is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,[28] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. The Exchange's proposal requires the value of the index or portfolio underlying an ETF based on a global or international index to be disseminated at least once every 60 seconds during Exchange trading hours.[29] Furthermore, these generic listing standards provide that the issuer of an ETF must represent that it will calculate the NAV and make it available daily to all market participants at the same time.[30] In addition, an IIV, which represents an estimate of the value of a share of each ETF, must be updated and disseminated at least once every 15 seconds during the time an ETF trades on the Exchange.[31] The IIV will be updated to reflect changes in the exchange rate between the U.S. dollar and the currency in which any index or portfolio component stock is denominated.[32] When there is no overlap with the trading hours of the primary market or markets trading the underlying components of an ETF,

[22] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78s(b)(1).

[25] 17 CFR 240.19b–4.

[26] The Commission notes, however, that the failure of a particular ETF to meet these generic listing standards would not preclude the Exchange from submitting a separate proposed rule change to list and trade the ETF.

[27] *See* Securities Exchange Act Release No. 55269 (February 9, 2007), 72 FR 7490 (February 15, 2007) (SR–Nasdaq–2006–050); Securities Exchange Act Release No. 55113 (January 18, 2007), 72 FR 3179 (January 24, 2007) (SR–NYSE–2006–101); and Securities Exchange Act Release No. 54739 (November 9, 2006), 71 FR 66993 (November 17, 2006) (SR–Amex–2006–78).

[28] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[29] *See* proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(b)(2) and 8.100, Commentary .01(b)(3). If an index or portfolio value does not change for some of the time that the ETF trades on the Exchange, the last official calculated value must remain available throughout Exchange trading hours.

[30] *See* proposed NYSE Arca Equities Rules 5.2(j)(3)(A)(v) and 8.100(e)(1)(ii).

[31] *See* proposed NYSE Arca Equities Rules 5.2(j)(3), Commentary .01(c) and 8.100, Commentary .01(c).

[32] *See id.*

NYSE Arca may trade such ETF during the Opening Session without an IIV being updated, as long as the last official calculated IIV remains available. Although the IIV is not calculated during the Late Trading Session, the last official calculated IIV must also remain available during such session. The Commission believes that the proposed rules regarding the dissemination of the index value and the IIV are reasonably designed to promote transparency in the pricing of ETFs and thus are consistent with the Exchange Act.

Similarly, the Exchange's trading halt rules are reasonably designed to prevent trading in an ETF when transparency cannot be assured. Proposed NYSE Arca Equities Rule 5.5(g)(2)(b) provides that, when the Exchange is the listing market, if the IIV or index value applicable to an ETF is not disseminated as required, the Exchange may halt trading during the day in which the interruption occurs. If the interruption continues, the Exchange will halt trading no later than the beginning of the next trading day.[33] This proposed rule is substantially similar to those recently adopted by other exchanges and found by the Commission to be consistent with the Exchange Act.[34]

In approving this proposal, the Commission relied on NYSE Arca's representation that its surveillance procedures are adequate to properly monitor the trading of the Units and PDRs listed pursuant to the proposed new listing standards or traded on a UTP basis. This approval is conditioned on the continuing accuracy of that representation.

Acceleration

The Commission finds good cause for approving the proposed rule change, as amended, prior to the 30th day after the date of publication of the notice of the amended proposal in the **Federal Register**. The Commission notes that NYSE Arca's proposal is substantially similar to other proposals that have been approved by the Commission.[35] The Commission does not believe that NYSE Arca's proposal raises any novel regulatory issues and, therefore, that good cause exists for approving the filing before the conclusion of a notice-and-comment period. Accelerated approval of the proposal will expedite the listing and trading of additional ETFs by the Exchange, subject to consistent and reasonable standards. Therefore, the Commission finds good cause, consistent with Section 19(b)(2) of the Exchange Act,[36] to approve the proposed rule change, as amended, on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[37] that the proposed rule change (SR–NYSEArca–2006–86), as amended, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[38]

Nancy M. Morris,

Secretary.

[FR Doc. E7–7324 Filed 4–17–07; 8:45 am]

BILLING CODE 8010–01–P

[33] In addition, NYSE Arca Equities Rule 7.34 sets forth trading halt procedures when the Exchange trades ETFs pursuant to UTP.

[34] *See e.g.*, Securities Exchange Act Release No. 54997 (December 21, 2006), 71 FR 78501 (December 29, 2006) (SR–NYSEArca–2006–77).

[35] *See supra* note 27.

[36] 15 U.S.C. 78s(b)(2).

[37] *Id.*

[38] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Public Federal Regulatory Enforcement Fairness Hearing; Region I Regulatory Fairness Board

The U.S. Small Business Administration (SBA) Region I Regulatory Fairness Board and the SBA Office of the National Ombudsman will hold a National Regulatory Fairness Hearing on Tuesday, May 1, 2007, at 1 p.m. The forum will take place at the Rhode Island Convention Center, 1 Sabin Street, Room 558, Providence, RI 02903. The purpose of the meeting is for Business Organizations, Trade Associations, Chambers of Commerce and related organizations serving small business concerns to report experiences regarding unfair or excessive Federal regulatory enforcement issues affecting their members.

Anyone wishing to attend or to make a presentation must contact Norm Deragon, in writing or by fax in order to be placed on the agenda. Norm Deragon, Public Information Officer, SBA, Providence District Office, 380 Westminster Street, Room 511, Providence, RI 02903, phone (401) 528–4561, Ext. 4576 and fax (401) 528–4539, e-mail: *Norm.deragon@sba.gov.*

For more information, see our Web site at *http://www.sba.gov/ombudsman.*

Matthew Teague,

Committee Management Officer.

[FR Doc. E7–7363 Filed 4–17–07; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

FAA Approval of Noise Compatibility Program 14 CFR Part 150; Spirit of St. Louis Airport, Chesterfield, MO

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by St. Louis County under the provisions of 49 U.S.C. (the Aviation Safety and Noise Abatement Act, hereinafter referred to as ''the Act'') and 14 CFR part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On December 12, 2006, the FAA determined that the noise exposure maps submitted by St. Louis County under Part 150 were in compliance with applicable requirements. On April 6, 2007, the FAA approved the Spirit of St. Louis Airport noise compatibility program. All but one of the recommendations of the program was approved.

DATES: *Effective date:* The effective date of the FAA's approval of the Spirit of St. Louis Airport noise compatibility program is April 6, 2007.

FOR FURTHER INFORMATION CONTACT: Mark Schenkelberg, 901 Locust, Kansas City, Missouri, 816–329–2645. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for Spirit of St. Louis Airport, effective April 6, 2007.

Under section 47504 of the Act, an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport

proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act and is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types of classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other power and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR Part 150, section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests for project grants must be submitted to the FAA Regional Office in Kansas City, Missouri.

St. Louis County submitted to the FAA on November 2, 2006, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from 2002 through 2006. The Spirit of St. Louis Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on December 12, 2006. Notice of this determination was published in the **Federal Register**, Vol. 71, No. 242, on December 18, 2006.

The Spirit of St. Louis Airport study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from 2006 to the year 2011. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 47504 of the Act. The FAA began its review of the program on December 12, 2006, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new or modified flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained thirteen proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the FAA effective April 6, 2007.

Outright approval was granted for twelve of the specific program elements. The extension of the north runway was disapproved for lack of noise benefit to noncompatible land uses exposed to noise levels of DNL 65 dBA.

These determinations are set forth in detail in a Record of Approval signed by the Central Region Airports Division Manager on April 6, 2007. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of St. Louis County. The Record of Approval also will be available on-line at *http://www.faa.gov/arp/environmental/14cfr150/index14.cfm.*

Issued in Central Region April 10, 2007.

George A. Hendon,

Central Region Airports Division Manager.

[FR Doc. 07–1906 Filed 4–17–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Virginia

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed highway project, Interstate 73 between Interstate 81 near the City of Roanoke and the Virginia/North Carolina State line south of the Town of Martinsville, in Roanoke, Franklin, and Henry Counties and the City of Roanoke, State of Virginia. Those actions grant approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 15, 2007. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Edward S. Sundra, Senior Street, Richmond, Virginia, 23219–4725 telephone: (804) 775–3338; e-mail: *Ed.Sundra@dot.gov.* The FHWA Virginia Division Office's normal business hours are 7 a.m. to 5 p.m. (eastern time). You may also contact Mr. Bruce McAuliffe, Engineering Programs Supervisor, Virginia Department of Transportation, 1401 East Broad Street, Richmond, Virginia 23219; telephone (804) 786–6757; e-mail: *Bruce.McAuliffe@vdot.virginia.gov*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final agency actions by issuing approvals for the following highway project in the State of Virginia: Interstate 73, between Interstate 81 near the City of Roanoke and the Virginia/North Carolina State line south of the Town of Martinsville, in Roanoke, Franklin, and Henry Counties and the City of Roanoke. The project covered by this notice will be approximately 116 km (72 mi) long and consists of improvements to existing Interstate 581 and U.S. Route 220 for approximately 9.7 k (6 mi) and construction on new location for approximately 106.3 km (66 mi). The project is part of the Interstate 73 high priority corridor that runs from Michigan to South Carolina, which was established by the U.S. Congress in 1991 with the passage of the Inter-modal Surface Transportation Efficiency Act. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final environmental Impact Statement (FEIS)

for the project, approved on December 1, 2006, in the FHAWA Record of Decision (ROD) issued on March 30, 2007, and in other documents in the FHWA administrative record file are available by contacting the FHWA or the Virginia Department of Transportation at the addresses provided above. The FHWA FEIS can be viewed and downloaded from the project Web site at *http://www.i73info.com/*.

This notice applies to all FHWA decisions and approvals as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Air: Clean Air Act, 42 U.S.C. 7401–7671(q).

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. Wildlife: Marine Mammal Protection Act [16 U.S.C. 1361], Fish Wildlife Coordination Act [16 U.S.C. 661–667(d), Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205 Highway Planning and Construction. The regulation implementing Executive Order 12372 regarding intergovernmental consultation on Federal program and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: April 6, 2007.

Edward Sundra,

Senior Environmental Specialist, Richmond, Virginia.

[FR Doc. 07–1914 Filed 4–17–07; 8:45 am]

BILLING CODE 4910–RY–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2006–24646]

Union Pacific Railroad Company; Notice of Public Hearing and Extension of Comment Period

The Union Pacific Railroad Company (UP) has petitioned the Federal Railroad Administration (FRA) seeking relief from the requirements of the Rules, Standards and Instructions found in Title 49 Code of Federal Regulations (CFR) Section 236.586, Daily or after-trip test. Specifically, UP is seeking to change the administration of the first sentence in paragraph (a) from ''intervals of not more than 2 months'' to ''intervals of not more than 92 days'' for all cab signal devices on locomotives operated by UP. This waiver application is identified as Docket Number FRA–2006–24646.

FRA issued a public notice seeking comments from interested parties. After examining the carrier's proposal and the submitted letters of protest from interested parties, FRA has determined that a public hearing is necessary before a final decision will be made on this proposal. Accordingly, a public hearing is hereby set for 9 a.m. on Thursday, May 31, 2007, at the Holiday Inn Express Hotel & Suites, 300 Holiday Frontage Road, in North Platte, Nebraska 69101. Interested parties are invited to present oral statements at the hearing.

The hearing will be informal and will be conducted by a representative designated by FRA in accordance with Rule 25 of the FRA Rules of Practice (49 CFR Section 211.25). The hearing will be a non-adversary proceeding and, as such, there will be no cross-examination of persons presenting statements. The FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements have been completed, persons wishing to make brief rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Any additional procedures, if necessary, will be announced at the hearing.

FRA is also extending the comment period to June 10, 2007. If information received at the public hearing warrants the need to extend the comment period further, a separate notice will be published indicating such extension.

All communications concerning these proceedings should identify the appropriate docket number (e.g.), Docket Number FRA–2006–24646) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC on April 12, 2007.

Michael J. Logue,

Deputy Associate of Administrator for Safety Compliance and Program Implementation.

[FR Doc. E7–7301 Filed 4–17–07; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket: PHMSA–98–4957]

Request for Public Comments and Office of Management and Budget Approval of an Existing Information Collection (2137–0614)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, PHMSA published a notice with request for comments in the **Federal Register** on February 12, 2007 (72 FR 6664) and

received no comments. PHMSA is now forwarding the information collection request to the OMB and providing an additional 30 days for comments.

DATES: Submit comments on or before May 18, 2007.

ADDRESSES: Send comments directly to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: Desk Office for the Department of Transportation, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Roger Little at (202) 366–4569, or by e-mail at *roger.little@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA requires each hazardous liquid operator to submit an annual report (49 CFR 195.49). Using PHMSA form F7000.1, each operator must provide details about the size and characteristic of their pipeline systems. This information helps PHMSA identify and evaluate potential pipeline safety problems to minimize hazardous liquid pipeline failures. Copies of the report form are available in the docket.

PHMSA invites comments on whether the proposed information collection is necessary for the proper performance of the functions of the Department. The term ''information collection'' includes all work related to the preparing and disseminating of information in accordance with the recordkeeping requirements. The comments should address (1) Whether the information will have practical utility; (2) the accuracy of the Department's estimate about the information collection burden; (3) ways to enhance the quality, utility, and clarity of the information collection; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

Type of Information Collection Request: Renewal of Existing Collection.

Title of Information Collection: Hazardous Liquid Pipeline Operator Annual Reports.

Respondents: 218 hazardous liquid pipeline operators completing 417 annual reports.

Estimated Total Annual Burden on Respondents: 5,004 hours.

Issued in Washington, DC on April 11, 2007.

Florence L. Hamn,

Director, Office of Regulations, Office of Pipeline Safety.

[FR Doc. 07–1930 Filed 4–17–07; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Privacy Act of 1974, as Amended

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Notice of proposed alterations to six Privacy Act systems of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of the Treasury, Office of Thrift Supervision (OTS), gives notice of proposed alternations to six Privacy Act systems of records, as follows: OTS .002—Correspondence/Correspondence Tracking; OTS .003—Consumer Complaints; OTS .006—Employee Locator File; OTS .008—Employee Training Database; OTS .011—Positions/Budget; OTS .012—Payroll/Personnel Systems & Payroll Records.

DATES: Comments must be received no later than May 18, 2007. The proposed altered systems will become effective May 29, 2007, unless the OTS receives comments which cause reconsideration of this action.

ADDRESSES: Comments should be sent to the Office of Chief Counsel, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552. To arrange to see the comments, see **FOR FURTHER INFORMATION CONTACT** below.

FOR FURTHER INFORMATION CONTACT: Dirk S. Roberts, Special Counsel, at (202) 906–7631 or by electronic mail, *dirk.roberts@ots.treas.gov.*

SUPPLEMENTARY INFORMATION: The OTS currently maintains nine Privacy Act systems of records. Notices describing these systems of records were most recently published at 70 FR 41085, July 15, 2005. The OTS proposes to add two routine uses to each of the six systems identified above authorizing disclosures in connection with litigation, as follows.

Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding. To assure that the agency and its employees receive appropriate representation in legal proceedings, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

In addition, OTS proposes to add two additional routine uses to one system identified above, OTS .012 Payroll/Personnel Systems & Payroll Records, authorizing disclosure relating to garnishment orders, as follows:

Information may be disclosed to respond to government authorities in connection with garnishment proceedings. Information may be disclosed to private creditors for the purpose of garnishment of wages of an employee if the debt has been reduced to a judgment.

The report of the altered systems of records, as required by 5 U.S.C. 552a(r) of the Privacy Act, has been submitted to the Committee on Government Reform of the House of Representatives, the Committee on Homeland Security and Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix I to OMB Circular A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated November 30, 2000.

The six proposed altered systems of records, described above, are published in their entirety below.

Dated: April 11, 2007.

Wesley T. Foster,

Acting Assistant Secretary for Management.

TREASURY/OTS .002

SYSTEM NAME:

Correspondence/Correspondence Tracking.

SYSTEM LOCATION:

Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

White House and Executive Office of the President officials, Members of Congress, Treasury Department officials, the general public, and businesses.

CATEGORIES OF RECORDS IN THE SYSTEM:

Incoming correspondence addressed to the Director of OTS, letters from members of Congress transmitting letters from constituents or making inquiries; OTS responses; OTS memoranda and notes used to prepare responses; and information concerning internal office assignments, processing and response to the correspondence.

PURPOSE(S):

To maintain written records of correspondence addressed to the Director of OTS and Congressional correspondence; to track the progress of the response; to document the completion of the response to the incoming correspondence.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) Disclosures may be made to a Congressional office from the records of an individual in response to an inquiry made at the request of the individual to whom the record pertains;

(2) Information may be disclosed to the appropriate governmental agency charged with the responsibility of administering law or investigating or prosecuting violations of law or charged with enforcing or implementing a statute, rule, regulation, order or license;

(3) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal, in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(4) To assure that the agency and its employees receive appropriate representation in legal proceedings, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media and in paper files.

RETRIEVABILITY:

Records are maintained by name of individual; assignment control number.

SAFEGUARDS:

Access to paper records is limited to authorized personnel with a direct need to know. Some paper records are maintained in locked file cabinets in a secured office with access limited to those personnel whose official duties require access. Access to computerized records is limited, through the use of a password, to those whose official duties require access.

RETENTION AND DISPOSAL:

Computerized records relating to non-congressional correspondence are retained for two (2) years after the Director's term. Computerized records relating to congressional correspondence are kept permanently. Paper records are retained for two (2) years after the Director's or member of Congress' term, then transferred directly to the National Archives.

SYSTEM MANAGER(S) AND ADDRESS:

Managing Director, Congressional Affairs, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in the system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Congressional letters and responses from a Member of Congress and/or a constituent.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/OTS .003

SYSTEM NAME:

Consumer Complaint System.

SYSTEM LOCATION:

(1) Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

(2) Northeast Region: Harborside Financial Center Plaza Five, Suite 1600, Jersey City, NJ 07311.

(3) Southeast Region: 1475 Peachtree Street, NE., Atlanta, GA 30309.

(4) Midwest Region: 225 E. John Carpenter Freeway, Suite 500, Irving, TX 75062.

(5) West Region: Pacific Plaza, 2001 Junipero Serra Boulevard, Suite 650, Daly City, CA 94014.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who submit inquiries or complaints concerning federally insured depository institutions, service corporations, and subsidiaries.

CATEGORIES OF RECORDS IN THE SYSTEM:

Consumer's name, savings association's docket number, case number as designated by a Consumer Complaint Case number. Within these categories of records, the following information may be obtained: consumer's address, source of inquiry or complaint, nature of the inquiry or complaint, nature of the inquiry or complaint designated by instrument and complaint code, information on the investigation and resolution of inquiries and complaints.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 57a(f), 5 U.S.C. 301.

PURPOSE(S):

OTS uses this system to track individual complaints and to provide additional information about each institution's compliance with regulatory requirements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) Information may be disclosed to officials of regulated savings associations in connection with investigation and resolution of complaints and inquiries:

(2) Relevant information may be made available to appropriate law enforcement agencies or authorities in connection with investigation and/or prosecution of alleged civil, criminal and administrative violations;

(3) Disclosures may be made to a Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Disclosures may be made to other Federal and nonfederal governmental supervisory or regulatory authorities when the subject matter is within such other agency's jurisdiction;

(5) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal, in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(6) To assure that the agency and its employees receive appropriate representation in legal proceedings, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper files and on electronic media.

RETRIEVABILITY:

By name of individual; complaint case number, savings association name, docket number, region complaint code, instrument code, source code or by some combination thereof.

SAFEGUARDS:

Paper records are maintained in locked file cabinets with access limited to those personnel whose official duties require access. Access to computerized records is limited, through use of the system passwords, to those whose official duties require access.

RETENTION AND DISPOSAL:

Active paper files are maintained until the case is closed. Closed files are retained six (6) years then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Consumer Protection and Specialized Programs, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in this system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Inquirer or complainant (or his or her representative which may include a member of Congress or an attorney); savings association officials and employees; compliance/safety and soundness examiner(s); and other supervisory records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/OTS .006

SYSTEM NAME:

Employee Locator File.

SYSTEM LOCATION:

(1) Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

(2) Northeast Region: Harborside Financial Center Plaza Five, Suite 1600, Jersey City, NJ 07311.

(3) Southeast Region: 1475 Peachtree Street, NE., Atlanta, GA 30309.

(4) Midwest Region: 225 E. John Carpenter Freeway, Suite 500, Irving, TX 75062.

(5) West Region: Pacific Plaza, 2001 Junipero Serra Boulevard, Suite 650, Daly City, CA 94014.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All present employees of the OTS and persons whose employment has been terminated within the last six months.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee's name, present address, telephone number, and the name, address, and telephone number of another person to notify in case of emergency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 44 U.S.C. 3101.

PURPOSE(S):

This system provides current information on employee's address and emergency contact person.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) Disclosure of information may be made to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(2) Medical personnel in case of an emergency;

(3) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(4) To assure that the agency and its employees receive appropriate representation in legal proceedings, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media.

RETRIEVABILITY:

Records are filed by name of individual.

SAFEGUARDS:

System access is limited to those personnel whose official duties require such access and who have a need to know information in a record for a particular job-related purpose.

Access to computerized records is limited, through use of a password, to those whose official duties require access.

RETENTION AND DISPOSAL:

Records are maintained until termination of employee's employment with OTS. After termination, records are retained for six months then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Human Resources, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in this system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

The individual whose record is being maintained.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/OTS .008

SYSTEM NAME:

Employee Training Database.

SYSTEM LOCATION:

Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All employees of the Office of Thrift Supervision.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual employee records are maintained by name, course taken, employee identification number, social security number, position, division, and manager name.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 44 U.S.C. 3101.

PURPOSE(S):

To maintain necessary information on training taken by employees through outside sources and vendors.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(2) To assure that the agency and its employees receive appropriate representation, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media.

RETRIEVABILITY:

Records are filed by individual name, employee identification number, social security number, and course taken.

SAFEGUARDS:

Access to computerized records is limited, through use of a password, to those persons whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with National Archives and Records Administration General Records Schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Manager, Professional Development, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in this system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Personnel records and individual development plans completed by employee and supervisor.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/OTS .011

SYSTEM NAME:

Positions/Budget.

SYSTEM LOCATION:

(1) Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

(2) Northeast Region: Harborside Financial Center Plaza Five, Suite 1600, Jersey City, NJ 07311.

(3) Southeast Region: 1475 Peachtree Street, NE., Atlanta, GA 30309.

(4) Midwest Region: 225 E. John Carpenter Freeway, Suite 500, Irving, TX 75062.

(5) West Region: Pacific Plaza, 2001 Junipero Serra Boulevard, Suite 650, Daly City, CA 94014.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All current employees of the Office of Thrift Supervision.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual employee records are kept by office and agency as follows: Name, title, entered on duty date, service computation date, occupation series, social security number, grade, current salary, location of employee, date of last promotion, and eligibility for promotion. Records are kept for each office (and, where appropriate, for the agency) on number of vacancies, authorized position ceilings, and number of employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 44 U.S.C. 3101.

PURPOSE(S):

The system allows the OTS Budget Division the ability to track positions by Office to assure that assigned Full-Time Equivalent ceilings are not exceeded and remain within the limits set by the Director of the OTS. The system also provides information to each office which can be used in developing their calendar year compensation budget.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) Information may be disclosed to the appropriate governmental agency charged with the responsibility of administering law or investigating or prosecuting violations of law or charged with enforcing or implementing a statute, rule, regulation, order, or license.

(2) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(3) To assure that the agency and its employees receive appropriate representation, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper files and on electronic media.

RETRIEVABILITY:

Records are filed by name of individual.

SAFEGUARDS:

Paper records are maintained in file folders in secured areas. Access is limited to personnel whose official duties require such access and who have a need to know the information in a record for a particular job-related purpose. Access to computerized

records is limited, through use of a password, to those whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with National Archives and Records Administration General Records Schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Managing Director, Information Systems, Administration and Finance, Office of Thrift Supervision, 1700 G Street, NW, Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in this system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/OTS .012

SYSTEM NAME:

Payroll/Personnel System & Payroll Records.

SYSTEM LOCATION:

(1) Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

(2) Northeast Region: Harborside Financial Center Plaza Five, Suite 1600, Jersey City, NJ 07311.

(3) Southeast Region: 1475 Peachtree Street, NE., Atlanta, GA 30309.

(4) Midwest Region: 225 E. John Carpenter Freeway, Suite 500, Irving, TX 75062.

(5) West Region: Pacific Plaza, 2001 Junipero Serra Boulevard, Suite 650, Daly City, CA 94014.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All current Office of Thrift Supervision (OTS) employees and all former employees of the OTS, within the past three years.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information pertaining to (1) employee status, grade, salary, pay plan, hours worked, hours of leave taken and earned, hourly rate, gross pay, taxes, deductions, net pay, location, and payroll history; (2) employee's residence, office, social security number, and address; (3) Personnel actions (SF–50), State employees' withholding exemption certificates, Federal employee' withholding allowance certificates (W4), Bond Allotment File (SF–1192), Federal Employee's Group Life Insurance (SF–2810 and 2811), Savings Allotment-Financial Institutions, Address File (OTS Form 108), Union Dues Allotment, time and attendance reports, individual retirement records (SF–2806), Combined Federal Campaign allotment, direct deposit, health benefits, and thrift investment elections to either the Federal Thrift Savings Plan (TSP–1) or OTS' Financial Institutions Thrift Plan (FITP–107 and K1–2).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 44 U.S.C. 3101.

PURPOSE(S):

Provides all the key personnel and payroll data for each employee which is required for a variety of payroll and personnel functions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

(1) In the event that records maintained in this system of records indicate a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of implementing the statute, or rule or regulation or order issued pursuant thereto;

(2) A record from this system may be disclosed to other Federal agencies and the Office of Personnel Management if necessary for or regarding the payment of salaries and expenses incident to employment at the Office of Thrift Supervision or other Federal employment, or the vesting, computation, and payment of retirement or disability benefits;

(3) A record from this system may be disclosed if necessary to support the assessment, computation, and collection of Federal, State, and local taxes, in accordance with established procedures;

(4) Disclosure of information may be made to a Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(5) Records from this system may be disclosed to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, for the purpose of locating individuals to establish paternity, establishing and modifying orders of child support, and identifying sources of income, and for other support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act (Welfare Reform Law, Pub. L. 104–193);

(6) Information may be disclosed in civil, criminal, administrative or arbitration proceedings before a court, magistrate, administrative or arbitration tribunal in the course of pre-trial discovery, motions, trial, appellate review, or in settlement negotiations, when OTS, the Director of OTS, an OTS employee, the Department of Treasury, the Secretary of Treasury, or the United States is a party or has an interest in or is likely to be affected by such proceeding and an OTS attorney determines that the information is arguably relevant to that proceeding;

(7) To assure that the agency and its employees receive appropriate representation in legal proceedings, relevant information may be disclosed to the Department of Justice, private counsel, or an insurance carrier for the purpose of defending an action or seeking legal advice;

(8) Information may be disclosed to respond to governmental authorities in connection with garnishment proceedings;

(9) Information may be disclosed to private creditors for the purpose of garnishment of wages of an employee if the debt has been reduced to a judgment.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media, microfiche, and in paper files.

RETRIEVABILITY:

Records are filed by individual name, social security number, and by office.

SAFEGUARDS:

Paper and microfiche records are maintained in secured offices and access is limited to personnel whose official duties require such access and who have a need to know the

information in a record for a particular job-related purpose. Access to computerized records is limited, through the use of a password, to those persons whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with National Archives and Records Administration General Records Schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Manager, Payroll and Travel, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals wishing to be notified if they are named in this system or gain access to records maintained in this system must submit a request containing the following elements: (1) Identify the record system; (2) identify the category and type of records sought; and (3) provide at least two items of secondary identification (date of birth, employee identification number, dates of employment or similar information). Address inquiries to FOIA Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

RECORDS ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Personnel and payroll records of current and former employees.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–7364 Filed 4–17–07; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0002]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0002'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005G2), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 565–8374, Fax (202) 565–7870 or e-mail *denise.mclamb@mail.va.gov*. Please refer to ''OMB Control No. 2900–0002.''

SUPPLEMENTARY INFORMATION:

Title: Veteran's Application for Pension, VA Form 21–527.

OMB Control Number: 2900–0002.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21–527 is completed by claimants who previously filed a claim for compensation and/or pension and wish to file a new claim for disability pension or reopen a previously denied claim for disability pension.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on December 21, 2006, at page 76725.

Affected Public: Individuals or Households.

Estimated Annual Burden: 104,440 hours.

Estimated Average Burden per Respondent: 60 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 140,440.

Dated: April 4, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E7–7335 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0675]

Agency Information Collection: Emergency Submission for OMB Review; Comment Request

AGENCY: Center for Veterans Enterprise, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the United States Department of Veterans Affairs (VA), has submitted to the Office of Management and Budget (OMB) the following emergency proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. 3507(j)(1)). The reason for the emergency clearance is to implement Public Law 109–461, Section 8127, the ''Veterans Benefits, Health Care and Information Technology Act of 2006'' which mandated Federal agencies to implement a verification program. VA will be requesting social security number or VA file/claim number to verify small businesses as veteran-owned or service-disabled veteran-owned. VA is requesting OMB to act on this emergency clearance request by May 25, 2007.

DATES: Comments must be submitted on or before May 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, (202) 395–7316. Please refer to ''OMB Control No. 2900–0675'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005G2), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 565–8374, fax (202) 565–7870 or e-mail *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0675.''

SUPPLEMENTARY INFORMATION:

Title: VetBiz Vendor Information Pages and VA Form 0877.

OMB Control Number: 2900–0675.

Type of Review: Revision of a currently approved collection.

Abstract: The Vendor Information Pages (VIP) will be used to assist federal agencies in identifying small businesses owned and controlled by veterans and service-connected disable veterans. This information is necessary to ensure that veteran owned businesses are given

the opportunity to participate in Federal contracts and receive contract solicitations information automatically. VA will use the data collected on VA Form 0877 to verify small businesses as veteran-owned or service-disabled veteran-owned.

Affected Public: Business or other for-profit, and Individuals or households.

Estimated Annual Burden: 5,000 hours.

Estimated Average Burden per Respondent:

VetBiz Vendor Information Pages—20 minutes.

VA Form 0877—5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 12,000.

Dated: April 5, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst Records Management Service.

[FR Doc. E7–7336 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0691]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to identify areas for improvement in clinical training programs.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov;* or to Mary Stout, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *mary.stout@va.gov.* Please refer to ''OMB Control No. 2900–0691'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mary Stout (202) 273–8664 or FAX (202) 273–9381.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Learner's Perception (LP) Survey, VA Form 10–0439.

OMB Control Number: 2900–0691.

Type of Review: New collection.

Abstract: VA Form 10–0439 will be used to obtain health care trainees perception of their clinical experience with VA versus non-VA facilities. VA will use the data to identify strengths and opportunities for improvement in VA clinical training programs.

Affected Public: Individuals or households.

Estimated Annual Burden: 2,250 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 9,000.

Dated: April 13, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E7–7337 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0092]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine a claimant's entitlement to vocational rehabilitation services.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0092'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the

burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Rehabilitation Needs Inventory, VA Form 28–1902w.

OMB Control Number: 2900–0092.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 28–1902w is mailed to service-connected disabled veterans who submitted an application for vocational rehabilitation benefits. VA will use data collected to determine the types of rehabilitation program the veteran will need.

Affected Public: Individuals or households.

Estimated Annual Burden: 35,000 hours.

Estimated Average Burden per Respondent: 60 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 35,000.

Dated: April 3, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E7–7343 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0698]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine claimants' eligibility for educational assistance to supplement tuition assistance.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov*. Please refer to ''OMB Control No. 2900–0698'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Application for Educational Assistance to Supplement Tuition Assistance; 38 CFR 21.1030(c), 21.7140(c)(5).

OMB Control Number: 2900–0698.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants who wish to receive educational assistance administered by VA to supplement tuition assistance administered by the Department of Defense must apply to VA. VA will use the data collected to determine the claimant's eligibility to receive educational assistance to supplement the tuition assistance he or she has received and the amount payable.

Affected Public: Not-for-profit institutions.

Estimated Annual Burden: 3,000 hours.

Frequency of Response: On occasion.

Estimated Average Burden per Respondents: 12 minutes.

Estimated Annual Responses: 15,000.

Dated: April 3, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E7–7345 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0696]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine whether payments provided to educational institutions and licensing and certification organizations are correct.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2007.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0696'' in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Availability of Educational, Licensing, and Certifications Records; 38 CFR 21.4209.

OMB Control Number: 2900–0696.

Type of Review: Extension of a currently approved collection.

Abstract: CFR 21.4209 requires educational institutions and licensing and certification organizations to make their records available to government representatives. VA will use the data collected to ensure that benefits paid under the education programs are correct.

Affected Public: Not-for-profit institutions.

Estimated Annual Burden: 6,000 hours.

Frequency of Response: On occasion.

Estimated Average Burden per Respondents: 5 hours.

Estimated Annual Responses: 3,000.

Dated: April 3, 2007.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Records Management Service.

[FR Doc. E7–7346 Filed 4–17–07; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Wednesday,
April 18, 2007

Part II

Environmental Protection Agency

40 CFR Part 174

Exemption Under the Federal Insecticide, Fungicide, and Rodenticide Act for Certain Plant-Incorporated Protectants Derived From Plant Viral Coat Protein (PVCP-PIPs) Gene(s); Supplemental Proposal; Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0642; FRL–8100–7]

RIN 2070–AD49

Exemption Under the Federal Insecticide, Fungicide, and Rodenticide Act for Certain Plant-Incorporated Protectants Derived From Plant Viral Coat Protein Gene(s) (PVCP-PIPs); Supplemental Proposal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to exempt from Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements plant-incorporated protectants derived from plant viral coat protein genes (PVCP-PIPs) when the PVCP-PIP meets specified criteria. EPA is proposing this exemption because the Agency believes that the PVCP-PIPs covered by this exemption would be of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act.

DATES: Comments must be received on or before July 17, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0642, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2006–0642. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Melissa Kramer, Hazard Assessment Coordination and Policy Division (7202M), Office of Science Coordination and Policy, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8497; fax number: (202) 564–8502; e-mail address: *kramer.melissa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Notice Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. Potentially affected entities may include, but are not limited to:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 32532), e.g., establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals;
- Crop Production (NAICS code 111), e.g., establishments primarily engaged in growing crops, plants, vines, or trees and their seeds;
- Colleges, Universities, and Professional Schools (NAICS code 611310), e.g., establishments of higher learning which are engaged in development and marketing of virus-resistant plants;
- Research and Development in the Physical, Engineering, and Life Sciences (NAICS code 54171), e.g., establishment primarily engaged in conducting research in the physical, engineering, or life sciences, such as agriculture and biotechnology.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR part 174. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0642. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Proposing?

EPA is proposing an exemption from FIFRA for certain plant virus coat protein plant-incorporated protectants or ''PVCP-PIPs.'' EPA is proposing to define a PVCP-PIP as ''a plant-incorporated protectant derived from one or more genes that encode a coat protein of a virus that naturally infects plants. This includes plant-incorporated protectants derived from one or more plant viral coat protein genes that produce only RNA and no virus-related protein.'' PVCP-PIPs introduced into plants with the intention of preventing or mitigating viral disease meet the FIFRA section 2(u) definition of ''pesticide'' because they are introduced into plants with the intention of ''preventing, destroying, repelling, or mitigating any pest...'' (7 U.S.C. 136(u)) and plant viruses meet the FIFRA section 2 definition of ''pest'' (7 U.S.C. 136(t)). EPA is proposing this exemption because the Agency believes that the PVCP-PIPs covered by this exemption would be of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act.

A PIP can be exempt from the requirements of FIFRA, other than the adverse effects reporting requirements of 40 CFR 174.71, if it meets all three of the requirements listed in 40 CFR 174.21. Section 174.21(a) requires that the PIP meet the criteria listed in at least one of the sections in §§ 174.25 through 174.50. Section 174.21(b) requires that when the PIP is intended to be produced and used in a crop used as food, the residues of the PIP are either exempted from the requirement of a tolerance under FFDCA or no tolerance would otherwise be required for the PIP. Section 174.21(c) requires that an exempt PIP must contain only those inert ingredient(s) included on the list codified at §§ 174.485 through 174.490. (Reference to §§ 174.485 through 174.490 in § 174.21(c) is proposed to be changed to refer to §§ 174.485 through 174.486 in today's Proposed Rule.) See Unit II.F. for further discussion of these § 174.21 criteria.

The rule proposed in today's **Federal Register** would establish 40 CFR 174.27, which would contain three criteria that, when met, would allow PVCP-PIPs to meet the general requirement for exemption for all PIPs listed at 40 CFR 174.21(a). Today's **Federal Register** also proposes to add several substances known to be used as inert ingredients in PIPs to 40 CFR part 174 subpart X, thereby potentially expanding the PVCP-PIPs that could meet the conditions of § 174.21(c). A companion document published elsewhere in today's **Federal Register** also proposes a tolerance exemption for certain PVCP-PIP residues, thereby potentially expanding the PVCP-PIPs that could meet the conditions of § 174.21(b).

The three criteria that EPA is proposing to insert at 40 CFR 174.27 are intended to address three issues that may be associated with a PVCP-PIP. These issues are:

- The potential for increased weediness or invasiveness of the crop plant containing the PVCP-PIP or any wild or weedy relatives that could acquire the PVCP-PIP through gene flow thereby causing negative effects on either the agro-ecosystem or natural environments. This issue is addressed in proposed § 174.27(a).
- The potential that viruses with novel properties could develop through novel viral interactions. This issue is addressed in proposed § 174.27(b).
- The potential for human or nontarget organism exposure to proteins that have not previously existed in nature and thus should be examined to determine whether they have potentially toxic or allergenic properties. This issue is addressed in proposed § 174.27(c).

In order to satisfy 40 CFR 174.21(a), a PVCP-PIP would have to satisfy proposed § 174.27(a), (b), and (c). The requirements at § 174.27(d) would also have to be met to qualify for exemption. Proposed § 174.27(a), (b), and (c) each can be met in one of two ways: a product developer may self-determine that paragraph (1) of the criterion applies (i.e., § 174.27(a)(1), (b)(1), or (c)(1)) or the Agency may determine that paragraph (2) of the criterion applies (i.e., § 174.27(a)(2), (b)(2), or (c)(2), respectively). Paragraph (1) of each proposed criterion (i.e., § 174.27(a)(1), (b)(1), and (c)(1)) describes an objective, well-defined characteristic. Therefore, the developer may determine whether the PVCP-PIP meets the requirement. Paragraph (2) of each proposed criterion (i.e., § 174.27(a)(2), (b)(2), and (c)(2)) is conditioned on an Agency determination because it may involve analysis of several types of information. Each criterion may be satisfied either by self determination under paragraph (1) or Agency determination under paragraph (2) irrespective of how the other two criteria are satisfied; there is no requirement that all three criteria must be satisfied under either paragraph (1) or paragraph (2) in order to qualify for the exemption.

B. What is the Agency's Authority for Taking this Action?

This rule is promulgated under the authority of FIFRA sections 3(a), 25(a), and 25(b) (7 U.S.C. 136a(a), 136w(a), and 136w(b)).

FIFRA section 3(a) states that, except as provided by the Act, no person may distribute or sell in the United States any pesticide that is not registered under the Act (7 U.S.C. 136(a)). FIFRA section 2(u) defines ''pesticide'' as: ''(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer...'' (7 U.S.C. 136(u)). Under FIFRA section 2(t), the term ''pest'' includes ''(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism... which the Administrator declares to be a pest...'' subject to certain exceptions (7 U.S.C. 136(t)).

Before EPA may register a pesticide under FIFRA, the applicant must show that the pesticide ''when used in accordance with widespread and commonly recognized practice... will not generally cause unreasonable adversese effects on the environment'' (7 U.S.C. 136a(c)(5)(D)). The term ''environment'' includes ''water, air, land, and all plants and man and other

animals living therein, and the interrelationships which exist among these'' (7 U.S.C. 136(j)). FIFRA section 2(bb) defines the term ''unreasonable adverse effects on the environment'' to mean: ''(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act'' (7 U.S.C. 136(bb)).

Although FIFRA requires the registration of most pesticides, it also authorizes the regulation of unregistered pesticides. FIFRA section 3(a) provides that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may limit the distribution, sale, or use of any pesticide that is not registered under section 3 of FIFRA, subject to an experimental use permit under section 5 of FIFRA, or subject to an emergency exemption under section 18 of FIFRA. Pesticides that are ''not registered'' include pesticides that are exempt from FIFRA requirements under section 25(b).

An unregistered pesticide may be distributed or sold if it is exempted by regulation under FIFRA section 25(b). Under FIFRA section 25(b)(2), the Agency can exempt pesticides from some or all of the requirements of FIFRA when the Agency determines that the pesticide is ''of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of this Act'' (7 U.S.C. 136w(b)(2)). EPA interprets section 25(b)(2) to authorize the Agency to exempt a pesticide or category of pesticides that EPA determines (1) poses a low probability of risk to the environment and (2) is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA. This standard differs from the standard for registration which considers only whether the pesticide ''when used in accordance with widespread and commonly recognized practice... will not generally cause unreasonable adverse effects on the environment'' (7 U.S.C. 136a(c)(5)(D)).

In evaluating the first condition that must be met for the Agency to exempt a pesticide, i.e., whether use of the pesticide poses a low probability of risk to the environment, EPA considers the extent of the potential risks caused by use of the pesticide to the environment, including humans and other animals, plants, water, air and land. Potential risks to humans include dietary risks as well as non-dietary risks such as those resulting from occupational or residential exposure to the pesticide. EPA uses the FFDCA section 408 standard in evaluating dietary risks as discussed in Unit II.C. of this preamble. EPA will not exempt pesticides unless they pose a low probability of risk to the environment.

In evaluating the second condition that must be met for the Agency to exempt a pesticide, i.e., whether the use of the pesticide is unlikely to cause unreasonable adverse effects on the environment even in the absence of regulatory oversight under FIFRA, EPA balances all the potential risks to human health, including dietary risks (see Unit II.C. of this preamble for discussion of the FFDCA standard), and risks to the remainder of the environment from use of the pesticide against the potential benefits associated with its use. In balancing risks and benefits, EPA considers the economic, social, and environmental costs and benefits of the use of the pesticide. If the pesticide poses a low probability of risk to the environment and is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA, EPA may exempt the pesticide from regulation under FIFRA.

C. What is the Relationship of FIFRA Exemptions to the FFDCA Section 408 Standard?

Under FFDCA section 408(a), a pesticide chemical residue in or on a food (hereafter simply ''in food'') is not considered safe unless EPA has issued a tolerance for the residue and the residue is within the established tolerance limit or EPA has issued an exemption from the requirement of a tolerance for the residue (21 U.S.C. 346a(a)(1)). FFDCA section 408 authorizes EPA to determine a residue is safe and therefore exempt from the requirement of a tolerance if the Administrator ''has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information'' (21 U.S.C. 346a(c)(2)(A)(ii)). Section 408 of the FFDCA also directs EPA to specifically consider harm that may result to infants and children as a result of pesticide chemical residues. For additional discussion of this standard, see the Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues of Plant Virus Coat Proteins that are Part of a Plant-Incorporated Protectant published concurrently in today's **Federal Register**.

EPA uses the FFDCA section 408 safety standard in evaluating whether a pesticide used in food meets the FIFRA section 25(b)(2) exemption standard with respect to human dietary risk. A pesticide in food poses a low probability of human dietary risk if it meets the FFDCA section 408 standard for an exemption from the requirement of a tolerance. Such a pesticide also is not likely to cause unreasonable adverse effects to the environment, with respect to human dietary risk only, if the dietary risks resulting from use of that pesticide are consistent with the FFDCA section 408 exemption standard, and the potential benefits of use outweigh any dietary risk even in the absence of regulatory oversight.

FIFRA, however, does not provide for exemption of a pesticide in food based solely upon human dietary risk and consistency with the FFDCA section 408 exemption standard; an exemption from the requirements of FFDCA does not exempt a product from regulation under FIFRA. For an exemption under FIFRA, EPA must also evaluate non-dietary risks to humans and the remainder of the environment from the pesticide and determine both that the pesticide poses only a low probability of non-dietary risks and that use of the pesticide is not likely to cause any unreasonable adverse effects to the environment from such nondietary risks in the absence of regulation.

D. What is the Role of Other Federal Agencies?

EPA is the Federal agency responsible for the regulation of pesticides. Under the Coordinated Framework for Regulation of Biotechnology (51 FR 23302, June 26, 1986), EPA works closely with the U.S. Department of Agriculture (USDA), which has responsibilities under the Plant Protection Act (PPA), and the U.S. Food and Drug Administration (FDA), which has responsibilities under FFDCA. EPA, USDA, and FDA consult and exchange information when such consultation is helpful in resolving safety questions. The three agencies also strive for consistency between programs following one of the basic tenets of the Coordinated Framework, i.e., that the agencies composing the Framework adopt consistent approaches to the extent permitted by the respective statutory authorities. A consistent approach between agencies is easier for the regulated community to understand, and it likely conserves resources

because data developed for one agency may meet at least some of the requirements posed by another agency for the same or similar products.

1. *USDA*. USDA has the responsibility of preventing the introduction and dissemination of plant pests under the PPA. Before a genetically engineered plant that is subject to the PPA may be introduced into the environment, approval must be obtained from the USDA/Animal Plant Health Inspection Service (APHIS) unless such a plant has been reviewed and granted Nonregulated Status. The USDA regulations use genetic engineering and potential plant pest risk as criteria for determining the scope of its regulations (62 FR 23945, May 2, 1997). Any genetically engineered plant that contains genetic material from a plant pest is subject to the regulations. Thus, all plants containing PVCP-PIPs are subject to USDA/APHIS requirements under the PPA.

EPA therefore recognizes that there is a potential for duplicative oversight with respect to certain issues that may arise in decisions about PVCP-PIPs that require any review by EPA. For example, in its reviews of Petitions for Determination of Nonregulated Status under regulations at 7 CFR part 340, the potential for weediness, for displacement of native species, and potential consequences of gene transfer are evaluated by USDA/APHIS. EPA and USDA/APHIS will continue to consult and collaborate on reviews of PVCP-PIPs. EPA and USDA/APHIS will work together to avoid potential duplication and inconsistencies and to coordinate their analyses in accordance with their respective expertise and jurisdiction.

2. *FDA*. FDA is the primary U.S. agency responsible for ensuring the safety of commercial food and food additives. FDA's authority under FFDCA extends to any nonpesticidal substance that may be introduced into a new plant variety and that is expected to become a component of food. Pursuant to sections 201 and 408 of FFDCA and the creation of EPA, pesticide chemical residues are subject to EPA's regulatory authority under FFDCA.

E. What is a PVCP-PIP?

EPA is proposing to define a PVCP-PIP as ''a plant-incorporated protectant derived from one or more genes that encode a coat protein of a virus that naturally infects plants. This includes plant-incorporated protectants derived from one or more plant viral coat protein genes that produce only RNA and no virus-related protein.''

Coat proteins are those substances that viruses produce to encapsulate and protect the viral nucleic acid and to perform other important tasks for the virus, e.g., assistance in viral replication, movement within the plant, and transmission of the virus from plant to plant by insects (Ref. 1). In many cases, when the genetic material encoding a plant virus coat protein is engineered into a plant's genome, the plant displays resistance to infection by that virus as well as other viruses having similar coat protein sequences (Ref. 2).

Current scientific information suggests that prevention or mitigation of disease by PVCP-PIPs may occur by two different mechanisms. For some PVCP-PIPs, resistance is believed to be protein-mediated because efficacy is correlated with the concentration of coat protein produced by the transgene (Ref. 3). In protein-mediated resistance, the coat protein is thought to impede the infection cycle by interfering with the disassembly of infecting viruses (Ref. 4).

In transgenic plants, a second mechanism of resistance, post-transcriptional gene silencing (PTGS) may be activated. In PTGS, prevention or mitigation of viral disease is not correlated with the level of coat protein expression. Indeed, virus resistance can occur even when a coat protein gene expresses untranslatable RNA sequences and no coat protein is detected (Ref. 4). PTGS is a defense mechanism in plants against foreign RNA (e.g., viruses) in which sequence-specific RNA degradation is initiated by the plant in response to the foreign RNA itself. Evidence suggests that PTGS is initiated once there is a threshold accumulation of double-stranded (ds) RNA in the cell cytoplasm (Ref. 5). Over 90% of plant viruses have single-stranded RNA genomes, but viral replication transiently produces dsRNA in quantities sufficient to trigger PTGS (Ref. 6). PTGS is also known to occur with transgenes that are transcribed at a low level but that likely produce dsRNA (Ref. 7). Once the plant recognizes the dsRNA, it is thought to be cleaved by a dsRNA-specific nuclease to produce small 21- to 25-nucleotide short interfering RNA sequences (siRNAs; Ref. 8). The siRNAs are thought to serve as guides for the cleavage of single-stranded RNA with a sequence similar to the dsRNAs (Ref. 9). Thus once PTGS is initiated, it targets all RNA with high sequence similarity to the sequence that initiated the process, regardless of whether it was transcribed from the transgene, an endogenous gene, or viral RNA.

A plant virus coat protein transgene that confers virus resistance through either a protein- or RNA-mediated mechanism would fall within EPA's proposed definition of a PVCP-PIP. The substances involved in either mechanism of resistance would meet the FIFRA definition of a pesticide because the transgene and any material expressed from the transgene are introduced into a plant for the purpose of preventing or mitigating viral disease (see Unit II.A.).

The proposed definition of a PVCP-PIP contains the phrase ''naturally infects plants.'' Including this phrase in the definition would specifically limit the proposed exemption by requiring that the virus coat protein gene sequence used in the PVCP-PIP be based exclusively on a plant virus sequence. This limitation is proposed in order to exclude from the definition any coat proteins of plant viruses that have been modified with sequences from animal or human viruses. EPA includes this concept in today's proposal in response to comment received from the public in earlier **Federal Register** documents pertaining to PVCP-PIPs.

F. What Conditions Must be Met for a PVCP-PIP to Qualify for a FIFRA Exemption?

As noted above, a PIP is exempt from the requirements of FIFRA, other than the adverse effects reporting requirements of 40 CFR 174.71, if the PIP meets the requirements in 40 CFR 174.21(a), (b), and (c). Therefore, the following factors need to be considered to determine the FIFRA status of a PVCP-PIP. First, does the PVCP-PIP meet the requirement at 40 CFR 174.21(a)? Second, do the residues of the PVCP-PIP meet the requirement at 40 CFR 174.21(b)? Third, do the inert ingredients that are part of the PVCP-PIP meet the requirement at 40 CFR 174.21(c)?

1. *Does the PVCP-PIP meet the requirement at 40 CFR 174.21(a)?* Section 174.21(a) requires that the PIP meet the criteria listed in at least one of the sections in §§ 174.25 through 174.50. Today's action proposes to establish § 174.27, which would contain criteria allowing certain PVCP-PIPs to meet the § 174.21(a) requirement for exemption. These criteria identify those PVCP-PIPs that EPA has been able to determine meet the standard under FIFRA section 25(b)(2), i.e., that pose a low probability of risk to the environment and that are not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA. EPA is proposing criteria that address the

relevant potential risks associated with these products:

i. The potential for increased weediness or invasiveness of the crop plant containing the PVCP-PIP or any wild or weedy relatives that could acquire the PVCP-PIP through gene flow thereby causing negative effects on either the agro-ecosystem or natural environments. This issue is addressed at § 174.27(a) and is referred to as ''weediness'' for the purposes of this document.

ii. The potential for viruses with novel properties developing through novel viral interactions. This issue is addressed at § 174.27(b) and is referred to as ''viral interactions'' for the purposes of this document.

iii. The potential for human or nontarget organism exposure to proteins that may not have previously existed in nature and thus should be examined to determine whether they have potentially toxic or allergenic properties. This issue is addressed at § 174.27(c) and is referred to as ''protein production'' for the purposes of this document.

Proposed §§ 174.27(a), (b), and (c) are discussed in greater detail in Unit III of this **Federal Register** document. In addition, a graphical depiction of what this rule is proposing is available in the docket for this proposed rule.

2. *Do the residues of the PVCP-PIP meet the requirement at 40 CFR 174.21(b)?* Section 174.21(b) requires that in order to qualify for a FIFRA exemption, the residues of a PVCP-PIP that is intended to be produced and used in a crop used as food must either be exempted from the requirement of a tolerance under FFDCA or no tolerance would otherwise be required for the PVCP-PIP. Therefore, if a PVCP-PIP is used in a food plant (e.g., the PVCP-PIP is produced and used in a corn plant) or residues of the PVCP-PIP might reasonably be expected in food (e.g., the PVCP-PIP is produced and used in an ornamental plant but could move through gene flow to a sexually compatible food plant), the FFDCA section 408 requirements must be considered when determining whether the PVCP-PIP can be exempted under FIFRA. If a PVCP-PIP would not be used in and would not reasonably be expected in a crop used as food (e.g., the PVCP-PIP is produced and used in an ornamental plant with no sexually compatible relatives that are food plants), the FFDCA section 408 requirements do not need to be considered.

EPA anticipates that in most cases the PVCP-PIP residues will consist of residues of nucleic acids, residues of inert ingredients, and residues of the plant virus coat protein portion of the PVCP-PIP (the ''PVC-protein''). Residues of nucleic acids are exempt from the requirement of a tolerance at 40 CFR 174.475. As of the time this proposed rule is being issued, residues of those inert ingredients that are exempt from the requirement of a tolerance are listed at 40 CFR part 180 and 40 CFR part 174 subpart W. In a companion piece appearing in today's **Federal Register**, EPA is proposing a tolerance exemption for residues of certain PVC-proteins that meet specified criteria. Due to different statutory requirements, the proposed FFDCA exemption criteria differ from the criteria proposed in this **Federal Register** for 40 CFR 174.27 under FIFRA.

3. *Do the inert ingredients that are part of the PVCP-PIP meet the requirement at 40 CFR 174.21(c)?* Section 174.21(c) requires that in order for a PIP to qualify for exemption any inert ingredient contained in the PIP must be codified at subpart X of 40 CFR part 174 - List of Approved Inert Ingredients. Subpart X lists the inert ingredients (i) that may be used in a plant-incorporated protectant listed in subpart B (Exemptions) of part 174 and (ii) whose residues are either exempted from the requirement of a tolerance under FFDCA or no tolerance would otherwise be required. EPA is proposing to add several substances known to be used commonly as inert ingredients in PIPs to 40 CFR part 174 subpart X. These substances already have tolerance exemptions under FFDCA. EPA proposes in today's **Federal Register** that these substances, when used in exempt PIPs as inert ingredients under specified conditions, should also be exempt from FIFRA because they are of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of the Act.

G. What if a PVCP-PIP Does Not Qualify for Exemption?

If EPA is unable to conclude that a PVCP-PIP meets the standard for exemption, an applicant may still apply to register the PVCP-PIP under section 3 of FIFRA. EPA may be able to conclude that the PVCP-PIP meets the standard for registration (i.e., when it is used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment). EPA recognizes that the proposed exemption criteria may not identify all low risk PVCP-PIPs. A case-by-case review for registration would allow the Agency to evaluate factors not readily incorporated into clear, unambiguous exemption criteria. As part of registration, the Agency could also impose conditions of use as appropriate. As is EPA's general practice regarding registration of PIPs, the Agency will consult with USDA in evaluating PVCP-PIPs for registration.

H. What is the History of this Proposal?

1. *Scientific input.* EPA sponsored or cosponsored with other Federal agencies, six conferences relevant to development of this proposed rule: on October 19–21, 1987, a meeting on ''Regulatory Considerations: Genetically Engineered Plants'' at Cornell University in Ithaca, New York; on September 8–9, 1988, a ''Transgenic Plant Conference'' in Annapolis, Maryland; on November 6–7, 1990, a conference on ''Pesticidal Transgenic Plants: Product Development, Risk Assessment, and Data Needs'' in Annapolis, Maryland; on April 18–19, 1994, a ''Conference on Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops'' in Annapolis, Maryland; on July 17–18, 1997, a ''Plant Pesticide Workshop'' in Washington, DC; and on December 10–12, 2001 a conference on ''Assessment of the Allergenic Potential of Genetically Modified Foods'' in Chapel Hill, North Carolina. EPA incorporated information from these conferences in development of this proposed rule as appropriate.

EPA has requested the advice of two scientific advisory bodies at five meetings while developing its approach to plant-incorporated protectants. On December 18, 1992, EPA convened a FIFRA Scientific Advisory Panel (SAP) to review a draft policy on PIPs (then called plant-pesticides) and to respond to a series of related questions posed by the Agency dealing primarily with EPA's approach under FIFRA. On July 13, 1993, EPA requested the advice of a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) on a series of scientific questions dealing with EPA's approach to PIPs under FFDCA. On January 21, 1994, EPA asked for advice on the Agency's approach to PIPs under both statutes at a joint meeting of the SAP and the BSAC. To evaluate more recent scientific advances, EPA again brought these issues to a FIFRA SAP meeting on October 13–14, 2004. On December 6–8, 2005, EPA convened a SAP meeting to address a series of scientific questions related to this proposal. EPA incorporated advice from all five meetings in development of this proposed rule as appropriate.

2. **Federal Register** *documents.* The history of this proposal consists of the original proposed exemption from

FIFRA requirements that appeared in the November 23, 1994 **Federal Register** (59 FR 60519); the original proposed exemption from FFDCA tolerance requirements in the November 23, 1994 **Federal Register** (59 FR 60545); and several supplemental documents appearing in the May 16, 1997 **Federal Register** (59 FR 27149), the July 22, 1996 **Federal Register** (61 FR 37891), the April 23, 1999 **Federal Register** (64 FR 19958), and the July 19, 2001 **Federal Register** (66 FR 37772 and 37855).

i. *November 23, 1994*. In a document that appeared in the November 23, 1994 **Federal Register** (59 FR 60519) (FRL–4755–3), EPA proposed two alternatives under FIFRA section 25(b)(2) to exempt PVCP-PIPs from FIFRA requirements. Option 1 proposed to categorically exempt plant-pesticides derived from coat proteins from plant viruses (now called PVCP-PIPs). Option 2 proposed a more limited exemption covering only those PVCP-PIPs that would have the least potential to confer selective advantage on free-living wild relatives of the plants that could acquire the PVCP-PIP through gene flow (discussed in detail in Unit III.C.3.).

Elsewhere in the November 23, 1994, **Federal Register** (59 FR 60545) (FRL–4755–4), EPA proposed to exempt from the FFDCA requirement of a tolerance, residues of plant virus coat proteins produced and used in living plants as a plant-incorporated protectant (then called a plant-pesticide). The proposed exemption from the requirement of a tolerance read, ''Residues of coat proteins from plant viruses, or segments of the coat proteins, produced in living plants as plant-pesticides are exempt from the requirement of a tolerance'' (59 FR 60547).

ii. *May 16, 1997*. In August of 1996, Congress enacted the Food Quality Protection Act (FQPA), which amended FFDCA and FIFRA. On May 16, 1997, EPA published a supplemental document in the **Federal Register** (62 FR 27149) (FRL–5716–6) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA applied to the 1994 proposed exemption from the requirement of a tolerance for residues of viral coat proteins produced in plants as part of a PIP. (Today's **Federal Register** terms such entities ''PVC-proteins.'')

In the 1997 supplemental document, EPA explained how most of the substantive factors that the amended FFDCA requires EPA to consider in evaluating pesticide chemical residues had been considered in the Agency's 1994 proposed tolerance exemption. Even though the Agency may not have used the terminology specified in the FQPA, EPA did take into account most of the factors (e.g., toxicity and consumption patterns) in issuing its 1994 proposal to exempt residues of PVC-proteins, or residues of segments of such proteins, from FFDCA tolerance requirements. EPA therefore sought comment on the requirements imposed by FQPA that the Agency had not addressed in its 1994 proposal, specifically:

a. EPA's conclusion that there are no substances outside of the food supply that may have a cumulative toxic effect with residues of PVC-proteins,

b. EPA's conclusion that there are no substances outside of the food supply to which humans might be exposed through non-occupational routes of exposure that are related via a common mechanism of toxicity to residues of PVC-proteins,

c. Any available information on PVC-proteins causing estrogenic effects,

d. EPA's rationale, described in greater detail, for concluding that PIPs are likely to present a limited exposure of pesticidal substances to humans in which the predominant route of exposure will be dietary, and

e. EPA's rationale, described in greater detail, for concluding that the Agency's analysis concerning the dietary safety of food containing PVC-proteins applies to infants and children as well as adults.

Because of the 1996 FQPA, EPA's final determination under FIFRA for PVCP-PIPs in food plants could also be affected by comments on the companion document in today's **Federal Register** that proposes a tolerance exemption for certain PVCP-PIP residues.

iii. *July 22, 1996*. On July 22, 1996, EPA issued a supplemental document (61 FR 37891) (FRL–5387–4) requesting comment on one aspect of its November 23, 1994 **Federal Register** document: how the concept of inert ingredient related to plant-incorporated protectants.

iv. *April 23, 1999*. On April 23, 1999, EPA published a supplemental document in the **Federal Register** (64 FR 19958) (FRL–6077–6) soliciting comment on whether to change the name of pesticides produced and used in living plants.

v. *July 19, 2001*. In July of 2001, EPA published a package of notices related to PIPs in the **Federal Register**, including a supplemental document (66 FR 37855) (FRL–6760–4) that provided the public with additional opportunity to comment on the FIFRA and FFDCA exemptions for PIPs that the Agency proposed in 1994 but had not yet finalized by 2001. EPA also requested comment on the information, analyses, and conclusions pertaining to these PIPs (including PVCP-PIPs) contained in the NRC report entitled ''Genetically Modified Pest-Protected Plants: Science and Regulation'' (Ref. 10). The public was given an opportunity to comment on a proposal to clarify the language of the original 1994 proposals EPA was considering in response to public comment received on the 1994 proposal. In addition, the Agency requested additional public comment on several scientific issues. Also in the July 19, 2001 **Federal Register** (66 FR 37772) (FRL–6057–7), EPA changed the name of these pesticides from ''plant-pesticides'' to ''plant-incorporated protectants'' or ''PIPs.''

The documents and reports of the meetings described above, including associated public comments, are available in the public dockets established for the associated rulemakings as described in Unit IX of this preamble.

Today's proposed rule completely supersedes these previous proposals. EPA does not intend to respond to comments submitted on those proposals. Thus, individuals who believe that any comments submitted on any of the earlier proposals remain germane to today's proposal, should submit them (or relevant portions) again during this comment period.

III. Proposed Exemption Criteria under § 174.27

A. Structure of the Proposed Exemption Criteria under § 174.27

In order to satisfy the general requirement for a FIFRA exemption listed at 40 CFR 174.21(a), EPA is proposing to add three criteria at 40 CFR 174.27. As discussed in Unit II.F.1., the three criteria that EPA is proposing to adopt at 40 CFR 174.27 are intended to address three issues that are associated with potential risks of PVCP-PIPs.

The PVCP-PIP would have to meet proposed §§ 174.27(a), (b), and (c) to satisfy 40 CFR 174.21(a). Proposed §§ 174.27(a), (b), and (c) each can be met in one of two ways: a product developer may self-determine that paragraph (1) of the criterion is met (i.e., § 174.27(a)(1), (b)(1), or (c)(1)) or the Agency may determine that paragraph (2) of the criterion is met (i.e., § 174.27(a)(2), (b)(2), or (c)(2), respectively). Paragraph (1) of each proposed criterion (i.e., § 174.27(a)(1), (b)(1), and (c)(1)) describes an objective, well-defined characteristic. Therefore, the developer may determine whether the PVCP-PIP meets the requirement. Paragraph (2) of

each proposed criterion (i.e., § 174.27(a)(2), (b)(2), and (c)(2)) is conditioned on an Agency determination because several types of information may need to be evaluated using a weight-of-evidence approach to determine whether the PVCP-PIP meets the requirement and is therefore of a nature warranting exemption.

1. *Exemption by self-determination*. Each criterion may be satisfied under either paragraph (1) or paragraph (2) irrespective of how the other two criteria are satisfied; there is no requirement that all three criteria must be satisfied under either paragraph (1) or paragraph (2) in order for a PVCP-PIP to qualify for the exemption. However, if a PVCP-PIP satisfies all three criteria under paragraph (1) by developer self determination (i.e., it meets proposed §§ 174.27(a)(1), (b)(1), and (c)(1)) and it satisfies §§ 174.21(b) and (c), EPA is proposing that the developer submit a notification to the Agency of that determination and certify that the PVCP-PIP qualifies for exemption under FIFRA, i.e., that the PVCP-PIP meets §§ 174.21(a), (b), and (c). In addition, EPA is proposing that the developer maintain information adequate to support the determination. Such records must be made available for EPA inspection and copying or be otherwise submitted to the Agency for review upon request for the duration of time that the PVCP-PIP is sold or distributed. EPA is proposing that these records be kept so that EPA could review a particular exemption determination if needed at a future date.

EPA is proposing to require that the notifications contain:

i. The name of the crop (including genus and species) containing the PVCP-PIP.

ii. The name of the virus from which the coat protein gene was derived.

iii. The name of the virus(es) to which resistance is conferred.

iv. When available, a unique identifier.

EPA is proposing this notification requirement because it provides a mechanism that allows the Agency to keep a record of all PVCP-PIPs that may be sold or distributed. EPA expects that such a list would be useful to developers whose products are moving in international trade because it would enable EPA to post information on the United States Regulatory Agencies Unified Biotechnology Website (found at *http://usbiotechreg.nbii.gov/database_pub.asp*) indicating that the developer has determined that the product satisfies the Agency's safety requirements. Such information can facilitate acceptance by importing countries. Absent such a posting, the field for EPA information would be blank, and importers might question the regulatory status of the product in the United States. In addition, EPA considers that such a list may be useful to the Agency for ensuring enforcement and compliance with FIFRA regulations because it will enable compliance personnel to ascertain the exemption status of products encountered in distribution and trade channels.

2. *Exemption by Agency determination*. If a PVCP-PIP does not satisfy a particular criterion under paragraph (1) (i.e., § 174.27(a)(1), (b)(1), or (c)(1)), EPA proposes that as an alternative route to exemption, the product developer would submit data or other information to the Agency to demonstrate that a particular PVCP-PIP meets paragraph (2) of that criterion (i.e., it meets § 174.27(a)(2), (b)(2), or (c)(2), respectively). In addition, as part of this submission, a developer would also include a certification as to any determination that the product meets § 174.27(a)(1), (b)(1), and/or (c)(1), as appropriate. During its review under § 174.27(a)(2), (b)(2), and/or (c)(2), EPA would not review the developer's determination that the product met any criterion under § 174.27(a)(1), (b)(1), or (c)(1).

EPA expects that in many instances developers would have most, if not all the information that would need to be included in any exemption submission under §§ 174.27(a)(2), (b)(2), or (c)(2) because it would have been gathered in the course of product development or for submission to USDA/APHIS as part of a petition for determination for non-regulated status. EPA will consult with USDA in evaluating whether a PVCP-PIP meets the conditions for an Agency-determined exemption. EPA is proposing that information supporting the submission be maintained as records that will be available for EPA inspection as necessary for the duration of time that the PVCP-PIP is sold or distributed.

EPA will evaluate the information contained in the submission and publish a notice allowing the public to comment on the Agency's determination that a product meets § 174.27(a)(2), (b)(2), and/or (c)(2), as appropriate. EPA is providing such a public comment period because even though the public will have had the opportunity to comment through this proposal on the appropriateness of the criteria in § 174.27(a)(2), (b)(2), and (c)(2), the public would not otherwise have an opportunity to comment on whether a particular PVCP-PIP meets these criteria, given that these determinations depend on a case-by-case analysis of several types of information.

The Agency plans to publish a **Federal Register** notice announcing its determination that a PVCP-PIP meets § 174.27(a)(2), (b)(2), and/or (c)(2), and if no adverse comments are received during the comment period, the Agency's decision will be considered final, and EPA will publish no further notice. Based on its experience with EUP notices, EPA expects that, in general, determinations that a PVCP-PIP qualifies for exemption will be noncontroversial and generate no adverse comments. However, in the case of adverse comments, EPA would publish a subsequent **Federal Register** notice announcing its final determination and address all public comments. EPA would prefer criteria in § 174.27(a)(2), (b)(2), and (c)(2) that would allow the public and PVCP-PIP developers to readily predict the outcome of an Agency review. Such criteria would reduce regulatory uncertainty in PVCP-PIP development and decrease the time EPA would need to evaluate the data/information necessary to make a determination that a PVCP-PIP meets a given criterion. However, using criteria for which determinations can be readily predicted might reduce the number of PVCP-PIPs that would qualify for exemption. EPA tried to balance these concerns and proposed multiple options when the Agency was unsure how to resolve this dilemma.

However, EPA does not believe that the considerations underlying its decisions to grant the public a further opportunity to comment on the Agency's decision apply in cases where the Agency rejects a submission for an exemption. Accordingly, if EPA determines that the product fails to meet one or more of the exemption criteria, EPA will provide notice to the applicant of its decision on the submission and that a registration would be required for the PVCP-PIP before the PVCP-PIP could be sold or distributed. The product developer may then submit an application for registration to the Agency. EPA would evaluate such PVCP-PIPs under the existing registration process and could implement conditions of use as appropriate.

B. Key Scientific Issues Associated with the Proposed Exemption Criteria under § 174.27

Several scientific questions concerning risk issues associated with PVCP-PIPs have been identified:

- What is the potential for a PVCP-PIP to endow plants with characteristics

that could disrupt the existing network of ecological relationships in managed, semi-managed, or natural ecosystems, e.g., through gene transfer to wild or weedy[1] relatives? This issue is addressed at proposed § 174.27(a) and is referred to as ''weediness'' for the purposes of this discussion.

• What is the potential for interactions between a PVCP-PIP and an infecting virus to affect plant virus epidemiology or pathogenicity? This issue is addressed at proposed § 174.27(b) and is referred to as ''viral interactions'' for the purposes of this discussion.

• What is the potential for exposure of humans or nontarget organisms to PVC-proteins with novel toxic or allergenic properties? This issue is addressed at proposed § 174.27(c) and is referred to as ''protein production'' for the purposes of this discussion.

These three questions are addressed below under the headings of weediness, viral interactions, and protein production, respectively.

C. Weediness

1. *Scientific issues.* In evaluating whether a PVCP-PIP could alter ecological relationships among plants, EPA considered two primary issues: (1) whether the PVCP-PIP could endow a transgenic plant itself with an increased ability to spread into natural or semi-managed habitats and (2) whether the transfer of a PVCP-PIP from a transgenic plant into wild or weedy relatives could endow the wild or weedy relative with increased competitive ability and thus disrupt ecological relationships. Gene transfer among sexually compatible plants is a natural phenomenon that EPA does not consider to be an environmental risk per se. Whether the transfer of a PVCP-PIP could significantly disrupt ecological relationships in specific instances depends on all of the following considerations: First, does the crop plant containing the PVCP-PIP have wild relatives with which it is able to hybridize in nature? If it does not, there can be no gene transfer. Second, if there are sexually compatible relatives, is the gene conferring virus resistance likely to become stable in the population? Third, is the stable introduction of a PVCP-PIP into the plant population (i.e., introgression) likely to cause the population to become more weedy/invasive or otherwise alter its competitive ability, thereby significantly changing the population dynamics of the plant community? The 2005 SAP concurred that these are important considerations for PVCP-PIPs by noting that an ''important ecological risk associated with gene flow from crop plants into their wild relatives is that the acquisition of crop genes might substantially alter the population dynamics of the wild plant. In particular, a transgene introgressed from the crop relative into a wild population might allow the wild species to persist in larger populations across a larger geographic range, or in a wider range of habitats. Collectively these changes in population dynamics can be considered 'increased weediness'. The probability that a particular transgene will lead to increased weediness depends on the phenotype conferred by the transgene and on the ecological factor(s) currently limiting the size or distribution of the wild species. In particular, if the transgene alters plant response to the ecological factor limiting population size, then population dynamics may be affected. For PVCP-PIPs, the relevant consideration is whether virus resistance (conferred by the PVCP-PIP) leads to changes in the size or distribution of wild plant species with the PVCP-PIP'' (Ref. 11).

i. *Likelihood that a crop plant containing a PVCP-PIP could itself disrupt ecological relationships.* In considering whether a PVCP-PIP could affect the ability of a plant to spread into natural or semi-managed habitat at the margins of cultivated fields, i.e., to form feral or naturalized populations, the key consideration is whether viral infection is currently limiting the ability of agricultural crops to do so. The 2005 SAP pointed out that PVCP-PIPs ''are developed when virus infection of a crop reduces the crop yield, suggesting that virus infection is quite likely in naturalized populations of the crop as well'' (Ref. 11). However, virus infection in crop plants does not necessarily limit the spread of the crop into natural or semi-managed areas. As the 2005 Panel also noted, ''little is known about factors controlling population size in plant populations in general, including those that are currently stable, as well as those that are currently weedy or invasive'' (Ref. 11). Few published studies are available that evaluate this question directly, perhaps due to the general rarity of negative results in scientific literature. However, one study did find virus infection to have little effect on an agricultural crop. Field experiments with transgenic virus-resistant sugar beets revealed no competitive advantage (measured as seedling emergence and biomass production) between the transgenic and susceptible control lines (Ref. 12).

Although virus infection has been shown to negatively impact growth and/or reproduction of some natural plant communities (discussed below in Unit III.C.1.ii.), EPA recognizes that there is reason to question whether the situation would be different for crop plants. The National Research Council (NRC) noted in 1989 that most naturalized, domesticated crops generally are unable to effectively compete with wild species in natural ecosystems and have not been known to acquire this ability with the type of single-gene traits commonly introduced through genetic modification (Ref. 13). The 1989 NRC report went on to note that plant breeders have capitalized for decades on the fact that relatively minor genetic changes can produce plants with altered ecological properties, but the addition of pest resistant traits has not been known to result in increased weediness of widely used crops (Ref. 13). A 1989 survey of the weedy characteristics of crop versus weed species showed that weeds possess significantly more weedy characteristics on average than do crop plants (Ref. 14). For domesticated crops, the traits that make them useful to humans also reduce their competitive ability in nonagricultural habitats. Crops that have been subjected to long-term breeding (e.g., corn and soybeans) are unlikely to possess characteristics that would allow the plant to compete effectively outside of managed ecosystems. Domesticity arises because intensive breeding efforts seek to eliminate many characteristics of the crop plant that would enhance weediness (e.g., seed shattering, thorns, seed dormancy, and bitterness). For example, lack of seed shattering and seed dormancy greatly reduces the ability of an annual crop to persist without human intervention. Highly domesticated crops such as corn are thus unlikely to survive for multiple generations outside agricultural fields no matter what transgenic trait they contain, including virus resistance (Ref. 15).

However, some crop species, e.g., cranberry and blackberry may have more similarities to their wild relatives than highly domesticated crops such as corn or soybean. As noted by the 2005

[1] In the context of the phrase ''wild and weedy'' relatives/plants used throughout this preamble, EPA considers weedy plants to be those with the characteristics of weeds, i.e., those that are considered undesirable, unattractive, or troublesome, especially when growing where they are not wanted. Wild plants are those that occur, grow, and live in a natural state and are not domesticated, cultivated, or tamed. EPA considers a naturalized population to be an enduring population of domesticated plants that grows in wild (non-cultivated) areas. EPA considers a native plant population to be one that originates in a particular region or ecosystem.

SAP, ''Determining whether a particular crop can naturalize and then spread as a weedy species is difficult to ascertain from the literature and determining the probability that a crop will be more weedy or invasive if it contains a PVCP-PIP is even more difficult'' (Ref. 11). Such determinations may therefore need to rely on information not available in public literature as part of a risk assessment for a particular plant. Plants, such as forest trees, that may grow for many years in natural environments or in very close proximity to natural environments present additional difficulty in evaluating and managing risks (Ref. 16). The period of time over which such plants would persist is significantly longer than for annual, short-lived species. Individual plants will therefore experience a much wider range and variety of stress conditions, enemy attacks, and climate change, making predictions about naturalization potential with acquired virus resistance particularly challenging.

Thus, although EPA believes that many crop species are unlikely to disrupt ecological relationships through acquisition of a PVCP-PIP, the available information is insufficient to support the general conclusions that EPA would need to make for a categorical exemption of PVCP-PIPs. EPA would need to conclude that there is a low risk that acquisition of a PVCP-PIP would significantly affect the competitiveness of any of the plants currently grown as crops and that none of these crop species would significantly disrupt ecological relationships when modified to contain a PVCP-PIP. Therefore, the Agency believes that it is necessary to evaluate each plant species independently to consider whether it is likely to establish weedy or invasive populations outside of agricultural fields in the United States and thereby potentially significantly disrupt ecological relationships if it becomes virus resistant due to a PVCP-PIP. Factors likely to influence this determination cannot be readily distilled into a straightforward criterion suitable for a categorical exemption.

ii. *Likelihood that a crop plant containing a PVCP-PIP could significantly disrupt ecological relationships through gene transfer*. The question of whether gene transfer from a crop to a wild or weedy relative could significantly disrupt ecological relationships is a more complicated question because a much broader range of potential plants may be involved when wild or weedy relatives are considered in addition to the crops themselves. The answer to this question depends first on the question of whether the transgenic crop plants could transfer a PVCP-PIP to other plant populations. This potential for transfer depends in part on the frequency of hybridization between domesticated species and their wild relatives. Hybridization is affected by the ability of plants to cross-pollinate which in turn is affected by their timing of reproductive viability and the proximity of the plants. Hybridization is also affected by the ability of pollen to fertilize recipient plants, the recipient plants to develop viable seeds, these seeds to germinate, and the seedlings to grow into viable adults (Ref. 17). In spite of these potential constraints, a survey of the world's most important crops suggests that spontaneous hybridization of domesticated plants with wild relatives appears to be a general feature across at least a portion of the worldwide geographic area over which each is cultivated (Refs. 18 and 19). The ability to cross crops with wild relatives (which may not necessarily occur where the crop is grown) is also the basis of many traditional breeding techniques that are used for virtually all crops (Ref. 20).

Whether virus infection limits the growth and/or reproductive ability of wild or weedy plant populations is more difficult to answer generically for all plants in all ecosystems. Viruses are pervasive in many natural plant populations (Refs. 21, 22, 23, and 24), although a comprehensive body of literature on the effect of viruses in weed species is lacking. According to the 2004 SAP, ''Our knowledge about the effect of virus infection on non-crop plants is quite limited'' (Ref. 25). Some published studies report that virus infection can have little or no effect on the plants. For example, a survey of *Plantago* species in England showed that although 92 of 144 plants were infected with one or more viruses, most of the plants showed no obvious disease symptoms (Ref. 23). A literature review of the role of weeds in the occurrence and spread of plant virus diseases describes several cases where viruses significantly damage certain crops but have little effect on their weed hosts (Ref. 26).

Other published studies have reported that infection reduces plant growth and/or fecundity. For example, naturally occurring tobacco leaf curl virus infection increases mortality and has negative effects on growth and seed output in plants from wild populations of the flowering perennial plant *Eupatorium chinense* (Ref. 27). Greenhouse experiments with this same plant under two irradiance levels showed that virus infection did not affect survivorship under high-light conditions but caused severe damage under low-light conditions (Ref. 28). Vegetative growth and flower production of purslane (*Portulaca oleracea*) was also reduced when plants were inoculated with cucumber mosaic virus (Ref. 29). Field experiments showed that wild cabbage plants (*Brassica oleracea*) inoculated with turnip mosaic virus or turnip yellow mosaic virus have reduced survival, growth, and reproduction (Ref. 30). Such experiments suggest that viruses can sometimes reduce individual plant growth and/or fecundity when infection occurs. However, individual-level effects are insufficient to understand population-level processes. For example, even if virus disease significantly affected individual plant fitness, a decline in individual-plant fitness might reduce competition such that uninfected plants could increase reproductive output, thereby mitigating any population-level effects (Ref. 31).

It can be difficult to predict the actual impact on overall plant population dynamics that would result from acquisition of virus resistance by plants that are in some way negatively affected by virus infection. EPA is not aware of any published study that has directly examined this question by, for example, purposefully freeing a plant species from virus infection and investigating the resulting population dynamics of infected versus uninfected plants. The 2004 SAP was also unaware of any such study, but offered that ''[b]ased on knowledge obtained from observation of cultivated crops in the agroecosystem, the majority of the Panel concluded that it would be unlikely that a plant population freed from viral pressure would give a plant species a competitive advantage'' (Ref. 25). Some members of the 2005 SAP agreed with the 2004 SAP, while ''[o]ther members of the current [2005] SAP believed, based on new information (Fuchs et al. 2004; Sukopp et al., 2005) not available to the 2004 Panel, as well as EPA indicating a lack of data on this topic, that concluding that viruses typically have no effect on their wild plant hosts is not accurate. Because of the differing opinions among the current [2005] Panelists, and the general paucity of data, the Panel cautioned that further research is needed to provide stronger support to this particular issue'' (Refs. 11, 32, and 33). EPA also notes that evaluating impacts on plant population dynamics is further complicated because in certain cases gene transfer of a PVCP-PIP to wild or weedy relatives might potentially be desirable. For example, an invasive virus species might be

effectively controlled through broad acquisition of resistance by plant species susceptible to the virus. Controlling disease outbreaks in perennial agricultural plants and trees could be significantly aided by reducing viral load in the environment through such approaches.

A few studies are available that are relevant to the question of whether acquisition of virus resistance could affect plant population dynamics. These studies show that in some cases virus infection can have such effects, suggesting that acquired virus resistance might as well. For example, infection with alfalfa mosaic virus substantially diminished the ability of certain medic cultivars to compete with other species such as capeweed in grazed pasture swards, both directly by decreasing the competitive ability of infected plants, and indirectly by altering the proportions in which the species germinated (Ref. 34). In another example of virus infection affecting plant population dynamics, growth analysis of *Eupatorium makinoi* revealed that plants naturally infected with a geminivirus had significantly reduced stem growth and plant height, along with decreased flowering and survivorship. This study suggests that in spite of the long-term coexistence of the virus and *Eupatorium makinoi*, such negative fitness attributes have a significant impact on at least some local plant populations in this species (Ref. 35).

Although relatively little research has been published regarding how plant population dynamics are directly influenced by virus infection, such results as described in the previous paragraph provide some support for the premise that virus resistance might be an important ecological fitness characteristic. At least some plant populations acquiring virus resistance might in some instances be able to better compete against other species (Ref. 36) and/or spread to habitats previously unsuitable because of the presence of the virus (Ref. 37). For example, a broad survey of geographic data on plant associations with viruses from published compendia and governmental or academic databases showed that plants were infected by 24% fewer viruses in their naturalized ranges than in their native ranges, supporting the hypothesis that the impact of invasive plants results in part from reduced natural enemy (e.g., virus) attack (Ref. 38). On the other hand, enemy release is only one of many hypotheses that could explain the abundance and/or impact of an invasive plant (Ref. 39). In addition, a few published studies have reported that in certain instances virus infection can increase plant fitness, suggesting that acquisition of virus resistance might decrease plant fitness. For example, infection by barley yellow dwarf virus was found in at least 1 year to increase the fitness of the host plant green foxtail (*Setaria viridis*) by approximately 25% (Ref. 40). In some cases, plants might be more attractive to herbivores when not infected by viruses, as was found to be the case for dusky coral pea (*Kennedya rubicunda*; Ref. 41). In this experiment, caged rabbits presented with a mixture of carrots and powdered plant extract grazed the mixture made from virus-free plant material at twice the rate as plant material infected with Kennedya yellow dwarf virus due presumably to greater palatability. In general, negative fitness attributes would be expected to be selected against in populations. Nevertheless, such considerations might be important in certain instances, e.g., when evaluating possible effects on endangered species.

EPA believes it likely that many of the potential PVCP-PIP/plant combinations pose a low risk of disrupting the existing network of ecological relationships in semi-managed or natural ecosystems. Multiple conditions must be met to pose a higher level of risk, i.e., hybridization with a wild relative must occur, introgression of the gene must occur, and acquired virus resistance must confer an advantage (or disadvantage) to the recipient plant sufficient to alter plant population dynamics. Nevertheless, the research discussed above showing that in some cases viruses can affect plant population dynamics for at least some plants highlights the difficulty in drawing a general conclusion as to whether all PVCP-PIP/plant combinations are likely to pose a low risk of significantly disrupting existing ecological networks. Virtually any crop could be modified to contain a PVCP-PIP, including less domesticated forage crops and trees, and such a wide range of plants will be associated with a concomitantly wide range of characteristics and behaviors. Ecosystems are highly complex and variable, and some of the factors that limit fitness of a given plant species can be subtle and are not well understood (Ref. 15). Consequently, EPA does not believe that the available body of evidence would currently support a definitive conclusion for all PVCP-PIPs that the potential transfer to wild or weedy relatives presents a low risk of significantly altering the network of ecological relationships in semi-managed or natural ecosystems.

Information may be available to evaluate the likelihood of acquired virus resistance impacting a particular plant species or population. However, the existing body of literature currently does not appear sufficient to describe any set of circumstances that would predict for the wide variety of possible PVCP-PIP/plant combinations whether introgression of the PVCP-PIP into a wild or weedy relative could change the population dynamics of the recipient plant and through this route potentially affect ecological relationships with other plants and other organisms in the community. For example, it is not possible to predict *a priori* whether a possible fitness advantage that individual plants might acquire with a PVCP-PIP would make the plant population better able to compete against other species. Whether population dynamics would be affected and ecological relationships could be disrupted in a given circumstance is dependent on multiple, interacting factors. In some instances, a weight-of-evidence, case-by-case review of information such as experimental data might allow such a determination; however, general knowledge of factors likely to influence population dynamics cannot be readily distilled into a straightforward criterion suitable for a categorical exemption.

2. *Proposed exemption criterion*. EPA is proposing § 174.27(a) based on a set of considerations articulated by the 2005 SAP to identify plants that would not pose concerns associated with increased weediness of either the crop plant itself or any sexually-compatible wild relatives, if the crop plant were to contain a PVCP-PIP. Section 174.27(a)(1) is a categorical exemption criterion for a subset of PVCP-PIPs, i.e., a list of plants that have already been determined by the Agency to be low risk with respect to concerns associated with weediness irrespective of the particular PVCP-PIP the plants might contain. Section 174.27(a)(2) is a conditional exemption criterion based on Agency review of whether a particular plant/PVCP-PIP combination poses low risk with respect to concerns associated with weediness. Both parts of § 174.27(a) are discussed in more detail in Units III.E.1.iii. and III.E.1.iv. below. Note that a PVCP-PIP qualifies for exemption based in part on its presence in a particular crop species. The record on which this proposed exemption is based is not currently broad enough to support an exemption for a PVCP-PIP in another species if that species has not been evaluated for concerns associated with weediness when it contains a particular

virus-resistant trait. A PVCP-PIP that has been moved into another species does not qualify for the exemption unless the recipient plant appears on the list in § 174.27(a)(1). Such a PVCP-PIP would either need an individual exemption determination under § 174.27(a)(2) or a registration in order to be sold or distributed.

i. *Proposed categorical exemption criterion in § 174.27(a)(1).* As articulated above, EPA does not believe it can propose a categorical exemption based on whether a PVCP-PIP/plant combination is likely to result in changes in plant population dynamics because this endpoint cannot easily be predicted based on straightforward characteristics of the PVCP-PIP and/or plant. However, EPA believes that a criterion for a categorical exemption could be developed based on evaluation of individual crop species for their potential to naturalize and invade natural ecosystems, including with acquisition of a PVCP-PIP and for the existence of wild or weedy relatives that could acquire a PVCP-PIP through gene flow. Certain plants are expected to pose low risk with respect to concerns associated with weediness regardless of any particular PVCP-PIP that the species contained. However, for the categorical exemption, the Agency is attempting to identify those situations where no case-by-case review is necessary to conclude that a PVCP-PIP would present a low risk of causing adverse effects. In such situations, a product developer could use a clearly defined criterion to make a determination of status. Based on these considerations, EPA has developed a list of plants that the Agency proposes a developer could use to self-determine whether § 174.27(a) is met.

A PVCP-PIP would meet proposed § 174.27(a) under § 174.27(a)(1) if the plant containing the PIP is one of the following: Anthurium (*Anthurium* spp.), asparagus (*Asparagus officinale*), avocado (*Persea americana*), banana (*Musa acuminata*), barley (*Hordeum vulgare*), bean (*Phaseolus vulgaris*), cacao (*Theobroma cacao*), carnation (*Dianthus caryophyllus*), chickpea (Cicer arietinum), citrus (*Citrus* spp., e.g., *Citrus aurantifolia*, *Citrus limon*, *Citrus paradisii*, *Citrus sinensis*), coffee (*Coffea arabica* and *Coffea canephora*), corn (*Zea maize*), cowpea (*Vigna unguiculata*), cucumber (*Cucumis sativus*), gerbera (*Gerbera* spp.), gladiolus (*Gladiolus* spp.), lentil (*Lens culinaris*), mango (*Mangifera indica*), orchids (*Orchidaceae*), papaya (*Carica papaya*), pea (*Pisum sativum*), peanut (*Arachis hypogaea*), pineapple (*Ananas comosus*), potato (*Solanum tuberosum*), soybean (*Glycine max*), starfruit (*Averrhoa carambola*), sugarcane (*Saccharum officinarum*), or tulips (*Tulipa* spp.).

EPA developed this list of plants after consultations with both the 2004 and 2005 SAPs. The 2004 SAP recommended a longer list of plants, chosen initially based on the presumption that they had no wild or weedy relatives in the United States. However, the 2005 SAP noted that the longer list of plants recommended by the 2004 SAP clearly contained ''some species that form viable crop-wild hybrids...'' (Ref. 11). Recognizing that much of the most useful information is not likely to be found in the literature, ''the Panel recommended consulting agronomists, breeders, and/or ecologists with specialized expertise before including any crop on a list of exempt species'' (Ref. 11). The 2005 Panel also recommended a specific set of conditions that each species would have to meet based on the advice of such experts (i.e., agronomists, breeders, and/or ecologists with specialized expertise) if it were to be placed on the list:

1. A crop should be included on the exempt list if it forms no viable hybrids with wild or weedy relatives anywhere in the US...
2. A crop should...be included on the exempt list only if it is [not] currently weedy or invasive...
3. A crop should be included on the exempt list if... it will not establish weedy or invasive populations if it becomes virus resistant (due to a PVCP-PIP)...
4. If a PVCP-PIP crop has the potential to naturalize, but the PVCP-PIP transgene is in biocontainment and/or biomitigation constructs that are stacked such that escapes from cultivation are too unfit to compete with the wild type, a consensus of breeders, agronomists, and ecologists, or others with experience with the species could advise addition to the list (Ref. 11).

EPA believes that the first three conditions proposed by the 2005 SAP are useful factors in evaluating whether a plant warrants inclusion on the list in § 174.27(a)(1). EPA considered each of these factors when evaluating each of the plants currently on the list in proposed § 174.27(a)(1). However, EPA also recognizes that plants that do not strictly meet condition 1 as laid out by the SAP may nevertheless be determined to pose low risk with respect to weediness concerns after a case-by-case review of the plants' traits and consideration of the whole range of factors that affect weediness. For example, corn may not meet the first condition above as articulated by the SAP if it proves to in fact have wild relatives in some region of the United States with which it can form viable hybrids. However, as discussed below, EPA does not believe that the characteristics of the wild relatives or the hybrids that could be formed suggest any reason to suspect acquired virus resistance would change the weediness potential of corn, the hybrid, or the wild relative, and EPA therefore proposes to include corn on the list. Thus, in practice EPA considers the 2005 SAP's first three conditions as a useful guide of the factors that should be taken into account in evaluating whether to include a plant on the list. However, EPA believes that relying on a strict interpretation of these conditions would exclude many plants containing PVCP-PIPs that meet FIFRA's low risk standard. The 2005 SAP itself suggested that some flexibility of interpretation might be appropriate. Although the Panel used the phrase ''no viable hybrids'' in condition 1, the Panel elsewhere recommended against granting exemption to crops with ''sexually compatible wild relatives'' where ''sexually compatible refers to the possibility of having crop transgenes backcross and introgress into the relative; it does not refer to sterile hybrids'' (Ref. 11).

Although EPA considered the first three conditions proposed by the 2005 SAP in deciding whether to include a particular plant species on the list in § 174.27(a)(1), EPA believes that the fourth condition as articulated would be inappropriate for these purposes. A biocontainment and/or biomitigation construct would be associated with a particular PVCP-PIP, not a particular plant species. The intent of § 174.27(a)(1) is to list species that would not present concerns related to weediness regardless of the particular PVCP-PIP that the species contained. EPA believes that construct-specific considerations could be taken into account under an Agency review procedure such as that described below in Unit III.C.2.iii.

The Panel recommended ''consulting agronomists, breeders, and/or ecologists with specialized (taxon-specific) expertise on weedy populations before including any crop on a list of exempt species'' because this information ''is difficult to ascertain from the literature and determining the probability that a crop will be more weedy or invasive if it contains a PVCP-PIP is even more difficult.'' Likewise, the Panel indicated ''[i]t is very difficult to identify crops that have no sexually compatible wild or weedy relatives in the US or its possessions and that do not become weedy or invasive themselves. This information is unique to each crop, is often not published, and is often known only by the agronomists, breeders, and

ecologists working with the specific taxa in question'' (Ref. 11). EPA agrees that such information is difficult to obtain from the literature and therefore relied on written consultation with such experts in evaluating whether the three conditions proposed by the 2005 SAP had been met for a particular crop species.

In consulting with experts for a particular crop, EPA asked at least three individuals a series of questions designed to address the issues identified by the 2005 SAP as relevant for evaluating whether a PVCP-PIP would be low risk with respect to concerns associated with weediness if it were to be found in the particular species. Specifically, EPA wanted to know:

• Does this crop form viable hybrids in nature (i.e., without human intervention) with wild or weedy relatives in the United States (including Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa)?

If yes, what species are they? Which of these species are themselves commercially grown crops? What is the frequency of hybrid production? Have hybrids demonstrated enhanced fitness (vigor) relative to parental varieties? Can the hybrids reproduce asexually? Are the hybrids sexually fertile?

If hybrids are sexually fertile, will they outcross or only backcross with the crop parent? How does the phenology of the crop species compare with the phenology of plant(s) with which it is sexually compatible? Are there any other attributes of these species that may enhance or inhibit sexual reproduction and species out-crossing?

• Is this crop known to become feral or easily spread into non-crop areas in the United States (including Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa)? If yes, have escaped plants formed reproducing and sustaining populations in non-crop areas? Where has this been known to happen? With what frequency is this likely to occur? Have feral populations required weed management activity?

• How likely is it that this crop would become feral or easily spread into non-crop areas if it acquired transgenic resistance to one or more viruses? What is the basis for your answer?

EPA focused these questions on ''non-crop areas'' to emphasize that the key consideration is a crop's behavior in natural settings. EPA recognizes that most crops within agricultural fields form volunteer populations, where propagules of the crop from the previous rotation grow in the subsequent crop rotation. The Agency did not consider behavior in crop areas when evaluating the crops for inclusion on the list at proposed § 174.27(a)(1).

The responses to specific Agency-posed questions received from these expert consultations are available in the docket for this proposed rule (Ref. 42). EPA considered the experts' responses in conjunction with other information when determining whether to list a crop at proposed § 174.27(a)(1), as discussed below. Crops that EPA evaluated but did not include in the proposed list for one reason or another are discussed in Unit VII where comment on these crops is specifically requested.

EPA notes that the 2005 SAP also suggested the Agency ''consider the geographic distribution of crops and their wild relatives when considering potential exemptions'' (Ref. 11). Although this is a potential option the Agency could pursue, a number of considerations limit the utility of using the potential for geographic isolation in determining whether a plant could be included on the list in § 174.27(a)(1). For example, EPA would need to consider carefully whether such isolation is likely to remain throughout the commercial life of the PVCP-PIP. Such isolation could occur if the crop containing the PVCP-PIP would not be commercially viable in the areas where wild relatives occur given biological considerations that are unlikely to change. However, geographic isolation could also be due to factors that may change throughout the commercial life of a PVCP-PIP, e.g., individual farmer choices of which crops to plant. Because of such considerations, EPA anticipates that it would only be able to support an exemption dependant on geographic restrictions where biological or similar factors provide assurance that the geographic isolation will remain constant during the entire commercial life of the PVCP-PIP.

The next several Subunits summarize EPA's conclusions to include the crops listed at proposed § 174.27(a)(1) based on consideration of the conditions suggested by the 2005 SAP and their recommendation that evaluation of these conditions be done in consultation with breeders, agronomists, and ecologists familiar with the particular species. The analyses below indicate that there is an extremely low probability that virus resistance conferred through a PVCP-PIP in any of these plants would significantly alter existing plant population dynamics or existing ecological relationships. The list is straightforward, providing an easy-to-understand criterion. Accordingly, EPA is proposing that a developer may self-determine whether a PVCP-PIP meets this criterion, i.e., whether the plant containing the PVCP-PIP is on the proposed list, because no further data or information would be needed to evaluate whether ecological relationships could be disrupted through increased weediness when the plant modified to contain the PVCP-PIP is on the list.

a. *Anthurium*. EPA proposes that anthurium (*Anthurium* spp.) be included on the list in § 174.27(a)(1) based on EPA consultations with anthurium experts. These consultations indicate that anthurium meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make anthurium weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''The commercial species [of] *Anthurium* (*Anthurium schezerianum and Anthurium andraenum*) have been grown outdoors since the early 1900's in semi-tropical and tropical areas of the US and there are no records of any commercial species escaping and becoming feral into non-crop areas. There is no reason to believe that acquiring transgenic resistance to one or more viruses would increase the ability of plants to become feral or easily spread into non-crop areas'' (Ref. 42). EPA therefore believes that anthurium meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

b. *Asparagus*. EPA proposes that asparagus (*Asparagus officinale*) be included on the list in § 174.27(a)(1) based on EPA consultations with asparagus experts. These consultations indicate that asparagus meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert said, ''Although volunteer asparagus plants may grow ''wild'' (i.e., not intentionally cultivated), they are not typically considered to be weeds. There are several horticultural varieties of asparagus, which could potentially be cross-pollinated. However, considering that asparagus is insect pollinated, this is likely to occur only in the rare situation where an asparagus grower also is growing horticultural varieties'' (Ref. 42). Second, the experts agreed that asparagus is not currently weedy or invasive outside of agricultural fields in

the United States. Two of the three experts indicated that asparagus can infrequently become feral. However, ''[a]sparagus is not typically considered to be a weedy species. In addition, since asparagus has separate male and female plants, it is considerably more difficult for ''wild'' populations to become established. Asparagus is also a relatively slow growing plant such that eradication (if necessary) would not be particularly onerous'' (Ref. 42). Third, these experts agreed that it is unlikely that acquisition of virus resistance would make asparagus weedy or invasive. For example, one expert stated, ''I have worked with this crop since 1978 and in all those years, I have not observed asparagus to become easily spread at all in non-crop or crop areas. Although asparagus does rarely grow wild in some areas (usually the temperate zones) asparagus is a very poor competitor with weeds and other plants and asparagus requires much attention and cultural care to thrive. I have only viewed a very rare occassionaly [sic] plant along fence rows and they usually are very weak and non-vigorous. Acquired transgenic resistance would do nothing to affect asparagus to become feral'' (Ref. 42). EPA therefore believes that asparagus meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

c. *Avocado*. EPA proposes that avocado (*Persea americana*) be included on the list in § 174.27(a)(1) based on EPA consultations with avocado experts. These consultations indicate that avocado meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make avocado weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated ''Transgenic resistance should not affect the likelihood of spread. Viral susceptibility is not an important factor limiting the plant's ability to become feral'' (Ref. 42). EPA therefore believes that avocado meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

d. *Banana*. EPA proposes that banana (*Musa acuminata*) be included on the list in § 174.27(a)(1) based on EPA consultations with banana experts. These consultations indicate that banana meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make banana weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated ''[i]t is highly unlikely that banana with acquired transgenic resistance would spread to non-crop areas because the probability of crossing is extremely small. Through vegetative propagation it will require man [sic] intervention just as non-transgenic plants'' (Ref. 42). EPA therefore believes that banana meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

e. *Barley*. EPA proposes that barley (*Hordeum vulgare*) be included on the list in § 174.27(a)(1) based on EPA consultations with barley experts. These consultations indicate that barley meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make barley weedy or invasive, as viruses are not consistently associated with failure of barley to show any evidence of being weedy or invasive. Three experts contacted by EPA indicated agreement with these statements. For example, one expert stated that he believes the likelihood that barley would become feral or easily spread into non-crop areas if it acquired transgenic virus resistance is ''negligible. Barley has been cultivated for decades in many U.S. environments, including environments that impose relatively mild disease pressure, particularly for viral diseases, such as the upper midwest and western states, and barley has not been able to establish itself in those regions as a feral species'' (Ref. 42). EPA notes that the 2005 SAP indicated that ''barley can hybridize with *Hordeum jubatum*, which is a weed in the USA'' (Ref. 11). However, three barley breeders consulted about this specific issue did not agree that hybridization was likely to occur. One stated, ''In relation to *Hordeum vulgare subsp. Vulgare* (cultivated barley) *Hordeum jubatum* is in the tertiary genepool. This means crossability is extremely difficult event under laboratory conditions'' (Ref. 42). A study that attempted to cross barley with two wild relatives, *H. murinum* L. and *H. jubatum* L., found that no hybridization occurred, even under favorable greenhouse conditions with forced pollination (Ref. 43). EPA therefore believes that barley meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

f. *Bean*. EPA proposes that bean (*Phaseolus vulgaris*) be included on the list in § 174.27(a)(1) based on EPA consultations with bean experts. These consultations indicate that bean meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert mentioned that ''[h]ybrids between Phaseolus vulgaris and Phaseolus acutifolius (tepary bean) are only achieved through extensive crossing and embryo rescue and thus is highly unlikely to occur in nature'' (Ref. 42). Another expert said bean would ''only - but rarely - hybridize with wild vulgaris (only where wild vulgaris occur, generally not in [the United States] & there are often biological barriers to such occurring'' (Ref. 42). Second, these experts agreed that bean is not currently weedy or invasive in the United States. Third, these experts agreed that it is unlikely that acquisition of virus resistance would make bean weedy or invasive. For example, one expert stated, ''Viruses generally do not prevent susceptible beans from making a crop (just the yield and quality of the crop is greatly reduced'' (Ref. 42). EPA therefore believes that bean meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

g. *Cacao*. EPA proposes that cacao (*Theobroma cacao*) be included on the list in § 174.27(a)(1) based on EPA consultations with cacao experts. These consultations indicate that cacao meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make cacao weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated that ''cacao is difficult to cultivate, the seeds are very susceptible to desiccation, and germination must occur within a few days or the seed die [sic]'' (Ref. 42). EPA therefore believes that cacao meets the conditions

recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

h. *Carnation*. EPA proposes that carnation (*Dianthus caryophyllus*) be included on the list in § 174.27(a)(1) based on EPA consultations with carnation experts. These consultations indicate that carnation meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. Two, it is not currently weedy or invasive in the United States. One expert indicated that Arkansas and Massachusetts have populations of feral *Dianthus caryophyllus*. However these have not required management activity because ''populations have remained small consisting of only a few plants'' (Ref. 42). Three, there is no reason to believe that acquisition of virus resistance would make carnation weedy or invasive. One expert stated, ''Most species of *Dianthus* are self-incompatible, and commercial selections of carnation require hand pollination, and set little viable seed. There is no record of carnation, *D. caryophyllus*, being naturalized or invasive in any part of the world'' (Ref. 42). EPA therefore believes that carnation meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

i. *Chickpea*. EPA proposes that chickpea (*Cicer arietinum*) be included on the list in § 174.27(a)(1) based on EPA consultations with chickpea experts. These consultations indicate that chickpea meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make chickpea weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated that ''there is no chance that chickpea would become feral with or without virus resistance. The susceptibility of the seeds to rotting without seed treatment would prevent any spread to non-crop areas. Resistance to viruses would not affect this outcome'' (Ref. 42). EPA therefore believes that chickpea meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

j. *Citrus*. EPA proposes that citrus (*Citrus* spp.) be included on the list in § 174.27(a)(1) based on EPA consultations with citrus experts. These consultations indicate that citrus meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert mentioned that citrus can hybridize with other *Citrus* species and certain other closely related species in the sub-family Aurantioidea. However, this expert also noted that it was unlikely to hybridize naturally with any of these species that are found in the United States because they are not closely related and ''would only be in the tertiary genepool for citrus'' (Ref. 42). Another expert pointed out that Rangpur lime is sometimes mentioned as native to Florida, but he did not think this was true; as far as he knew, there are no wild or weedy relatives of citrus found in the United States. Second, these experts agreed that citrus is not currently weedy or invasive in the United States. One expert mentioned that there are ''small feral populations of citrus found in Florida, mostly on the borders of the Everglades area and in some old forests.... However, these populations have not expanded their range. I know of no weed management efforts'' (Ref. 42). Third, these experts agreed that it is unlikely that acquisition of virus resistance would make citrus weedy or invasive. For example, one expert stated that ''citrus is simply not an aggressive grower with or without a virus'' (Ref. 42). EPA therefore believes that Citrus species meet the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

k. *Coffee*. EPA proposes that coffee (*Coffea arabica* and *Coffea canephora*) be included on the list in § 174.27(a)(1) based on EPA consultations with coffee experts. These consultations indicate that both species of coffee meet the three conditions outlined above by the SAP: They do not have wild or weedy relatives in the United States with which they can form viable hybrids in nature, they are not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make coffee weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''Coffee plantations that are abandoned usually decay and are not overtaken by coffee plants. The crop needs maintenance to grow properly. It is not a weedy species'' (Ref. 42). EPA therefore believes that coffee meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

l. *Corn*. EPA proposes that corn (maize; *Zea mays*) be included on the list in § 174.27(a)(1) based on EPA's extensive experience regulating PIPs in corn (Ref. 44), literature that is available on corn biology, the OECD Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (Ref. 45), and EPA consultations with corn experts (Ref. 42). OECD consensus documents are written by national experts who freely consult with breeders, agronomists, and ecologists who are specialists in the field. Each document must be reviewed and approved by experts in the 30 OECD member countries, and often by experts from non-OECD member countries. This body of information indicates that corn is low risk with respect to concerns associated with weediness.

EPA's 2001 risk assessment for *Bt* PIPs evaluated the potential for corn to form viable hybrids with wild or weedy relatives in the United States (Ref. 44). EPA's summary conclusion was that while wild relatives of corn (i.e., Eastern Gama Grass and teosintes) may exist in the United States, there is no significant risk of gene capture and expression of a PIP in any of these relatives. The potential for pollen-directed gene flow from corn to Eastern Gama Grass is extremely remote. This is evidenced by the difficulty with which *Tripsacum dactyloides* x *Zea mays* hybrids are produced in structured breeding programs. Additionally, the genus does not represent any species considered as serious or pernicious weeds in the United States or its territories. Any introgression of genes into this species as a result of cross fertilization with genetically modified corn is not expected to result in a species that is weedy or difficult to control. In many instances where hybridization has been directed between these two species, the resultant genome is lacking in most or all of the corn chromosomal complement in subsequent generations. Many of the *Zea* species loosely referred to as ''teosintes'' will produce viable offspring when crossed with *Zea mays* ssp. mays. None of these plants are known to harbor weedy characteristics, and none of the native teosinte species, subspecies, or races are considered to be aggressive weeds in their native or introduced habitats. In fact, many are on the brink of extinction where they are indigenous and will be lost without human intervention (i.e., conservation measures). Two of the three experts EPA consulted indicated that corn will not form viable hybrids with any wild or weedy relatives in the United States.

The third indicated that hybrids could be formed with teosintes, but that a hybrid ''would lose its seed dispersal ability, so would have highly diminished ability to propagate in the wild. In regions where teosinte is a weed (mostly in Mexico), the teosintes have been naturally selected to have 'gametophyte factors' (e.g., *Ga1-s, Tcb1*), that essentially block corn pollen from fertilizing teosinte'' (Ref. 42).

Further, the body of information and the experts that EPA consulted on corn indicate that it is not currently weedy or invasive in the United States. None of the landraces or cultivated lines of *Zea mays* are considered to have weedy potential, and all are generally considered to be incapable of survival in the wild as a result of breeding practices (i.e., selection) during domestication of the crop. According to the OECD consensus document, ''[m]aize has lost the ability to survive in the wild due to its long process of domestication, and needs human intervention to disseminate its seed. Although corn from the previous crop year can overwinter and germinate the following year, it cannot persist as a weed'' (Ref. 45). One expert EPA consulted stated, ''Maize does not become feral or spread easily into non-crop areas in the United States or its territories. During its domestication many centuries ago, maize lost many of the attributes necessary to sustain itself in nature'' (Ref. 42).

Finally, there is no reason to believe that acquisition of virus resistance would make corn weedy or invasive, as viruses are not consistently associated with failure of corn to show any evidence of being weedy or invasive. The experts EPA consulted agree that corn's becoming weedy with acquisition of a PVCP-PIP is unlikely. For example, one expert indicated, ''Domesticated maize has no seed dispersal mechanism. Humans are required to remove kernels from the cob (a typical cob holds 500–1,000 kernels, which would essentially try to all grow in the same spot, this would starve the resulting plants for nutrients and water and result in there being no progeny). Maize would essentially die out within a year or two, without human intervention'' (Ref. 42). EPA therefore believes that corn meets the conditions recommended by the 2005 SAP for inclusion on the § 174.27(a)(1) list and will present low risk with respect to weediness.

m. *Cowpea*. EPA proposes that cowpea (black-eyed pea; *Vigna unguiculata*) be included on the list in § 174.27(a)(1) based on EPA consultations with cowpea experts. These consultations indicate that cowpea meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert indicated, ''the cowpea is a highly self-pollinating crop that rarely outcrosses with other cowpeas. I expect that it might be possible for cowpea to rarely outcross with a 'wild' *V. unguiculata*, but it is probably safe to assume that the 'wild' cowpea genotypes don't exist in the United States'' (Ref. 42). Second, the experts agreed that cowpea is not currently weedy or invasive outside of agricultural fields in the United States. One expert said, ''I am not aware of any instance where the cowpea has become feral or easily spread into non-crop areas in the United States. HOWEVER, I am aware of instances where cultivated cowpea varieties have become weed pests in cultivated areas in the United States where OTHER CROPS are grown. For example, cowpea varieties with hard seeds can be a weed problem in soybean crops. The hard cowpea seeds over-winter in the soil and can produce plants in subsequent years; these cowpea plants often can't be easily killed by soybean herbicides (closely related plant) and the seeds are often so close in size to soybean seeds that [they] can be difficult to remove from the harvested soybean product'' (Ref. 42). However, EPA considers that the key consideration is the plant's behavior in natural settings, including semi-managed habitat surrounding agricultural fields, as opposed to its behavior within the fields themselves. Third, these experts agreed that it is unlikely that acquisition of virus resistance would make cowpea weedy or invasive. For example, one expert stated ''I am not aware of any virus problem in cowpea, if resolved via transgenic means, would result in the crop becoming feral'' (Ref. 42). EPA therefore believes that cowpea meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

n. *Cucumber*. EPA proposes that cucumber (*Cucumis sativus*) be included on the list in § 174.27(a)(1) based on EPA consultations with cucumber experts. These consultations indicate that cucumber meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make cucumber weedy or invasive. The experts contacted by EPA indicated agreement with these statements. For example, one expert stated that ''cucumber could not become feral due to acquired transgenic virus resistance. The failure for [cucumber] to survive without human intervention is not due to disease attack, but rather due to [its] ability to compete with native plants and weeds, and to withstand the stresses they are exposed to outside of cultivation, particularly drought'' (Ref. 42). EPA therefore believes that cucumber meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

o. *Gerbera*. EPA proposes that gerbera (*Gerbera* spp.) be included on the list in § 174.27(a)(1) based on EPA consultations with gerbera experts. Two experts indicated that there are no wild or weedy relatives in the United States with which gerbera can form viable hybrids in nature. A third said, ''*Gerbera jamesonii* Bolus ex Adlam has been recorded as naturalized in Florida. However, it is most likely *Gerbera hybrida* (*Gerbera jamesonii x G. viridiflora* Schultz-Bip) which is the designation for the commercially available *Gerberas*'' (Ref. 42). Regarding the ferality of gerbera species, two experts believed feral populations were not known to occur, while a third noted, ''Although *G. jamesonii* (or *G. hybrida*) is attributed to Florida, it is most likely a low risk for forming feral populations'' (Ref. 42). All three experts believed it unlikely that acquired virus resistance could lead to gerbera becoming feral or easily spreading into non-crop areas. One expert said, ''*Gerbera*, in general, is a short-lived perennial in the United States. It suffers from a number of fungal and bacteria pathogens. A transgenic virus-resistant *Gerbera* offers little in terms of [increased] fitness and increased invasive potential'' (Ref. 42).

p. *Gladiolus*. EPA proposes that gladiolus (*Gladiolus* spp.) be included on the list in § 174.27(a)(1) based on EPA consultations with gladiolus experts. These consultations indicate that gladiolus meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make gladiolus weedy or invasive. The experts contacted by EPA indicated agreement with these statements. For example, one expert said, ''No gladiolus species or hybrid has ever been documented as having successfully naturalized in the United

States. Virus resistance is not likely to make this any more likely'' (Ref. 42). EPA therefore believes that gladiolus meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

q. *Lentil*. EPA proposes that lentil (*Lens culinaris*) be included on the list in § 174.27(a)(1) based on EPA consultations with lentil experts. Although lentil was not on the list of plants recommended by the 2004 SAP, several experts consulted about other crops mentioned that lentil also appeared to meet the criteria that EPA was investigating. Consultations about lentil indicate that it meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make lentil weedy or invasive. The experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''Lentil could not possibly survive in the wild on its own. [Lentils are] rather delicate plants, small in stature and very weak in competition for space or water. It needs great care from grower [sic] to produce seeds in cultivation. Its seed could not possibly survive in the wild due to rotting by soil-born microorganisms. Resistance to one or more viruses will not increase the survivability of lentil seeds in the wild'' (Ref. 42). EPA therefore believes that lentil meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

r. Mango. EPA proposes that mango (*Mangifera indica*) be included on the list in § 174.27(a)(1) based on EPA consultations with mango experts. These consultations indicate that mango meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make mango weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''spread of mango seed by humans or animals into non-crop areas is rare and suitable environments are few. Transgenic resistance should not affect the likelihood of spread. Viral susceptibility is not an important factor limiting the plant's ability to become feral'' (Ref. 42). EPA therefore believes that mango meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

s. *Orchids*. EPA proposes that all genera of orchids in the family Orchidaceae be included on the list in § 174.27(a)(1) based on EPA consultations with orchid experts. These consultations indicate that orchids meet the three conditions outlined above by the SAP: They do not have wild or weedy relatives in the United States with which they can form viable hybrids in nature, they are not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make orchids weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''Species within these genera have specific insect pollinators and those insects are unlikely [to] be present for pollination in United States. In addition, species within these genera are very difficult to grow from seed without human intervention, requiring a symbiotic relationship with a specific fungal species. Acquiring transgenic resistance to one or more viruses would not affect pollination or seed germination'' (Ref. 42). EPA therefore believes that species in the orchid family meet the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

t. *Papaya*. EPA proposes that papaya (*Carica papaya*) be included on the list in § 174.27(a)(1) based on EPA consultations with papaya experts. These consultations indicate that papaya meets the three conditions outlined above by the SAP. First, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. Although *Carica papaya* has been successfully crossed with *Vasconellea* species using laboratory-based embryo rescue techniques, such hybrids do not form in nature (Ref. 42). Second, although all three breeding experts agreed that papaya is known to establish outside of agricultural areas through human- and animal-mediated seed dispersal, the species is not considered to be weedy or invasive. For example, one expert stated, ''I have observed small feral [papaya] populations in Guam, Hawaii and Puerto Rico... in areas close to human dwellings and activities.... The feral papayas are not weedy and are nonaggressive, they can easily be removed by cutting down.'' Further, as stated in USDA-APHIS' response to a petition for determination of nonregulated status for transgenic virus-resistant papaya, ''Papaya is not listed as a weed in the Federal Noxious Weed Act (7 U.S.C. 2801–2813) and is not reported by the Weed Society of America to be a common or troublesome weed anywhere in the United States (Bridges and Bauman, 1992; Holm *et al*. 1979; Muenscher, 1980)'' (Ref. 46). Third, two of three experts indicate there is no reason to believe that acquisition of virus resistance would make papaya weedy or invasive. The third expert said that it was ''[v]ery likely'' papaya would become feral or easily spread into non-crop areas if it acquired transgenic resistance to one or more viruses because ''[a]necdotal and informal reports at papaya conferences gave evidence that the virus resistance transgene was found in feral populations'' (Ref. 42). However, this comment seems to reflect the fact, as noted above, that papaya does occasionally form feral populations in spite of not being weedy or aggressive, and this characteristic would be expected whether the papaya is transgenic or not. In his comments to EPA, another expert concludes by saying that territorial records show papaya was not a weed in Hawaii prior to the discovery of papaya viruses in the 1940s. If papaya was not considered a weed prior to exposure to viruses, then there is no reason to believe that a virus resistant papaya would become a weed. Another expert corroborates this conclusion by stating, ''I see no competitive advantage of [virus-resistant] transgenic papayas over nontransgenic papayas.... Papaya requires high levels of human inputs to thrive or survive, including fertilizers, chemicals and care'' (Ref. 42). EPA therefore believes that papaya meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

u. *Pea*. EPA proposes that pea (*Pisum sativum*) be included on the list in § 174.27(a)(1) based on EPA consultations with pea experts. These consultations indicate that pea meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make pea weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''pea is not likely to become feral or easily spread into non-

crop areas due to acquired resistance to one or more viruses. Acquisition of transgenic viral resistance would not provide any adaptive advantage for survival of the transgenic crop plants. Peas have been produced in the US for more than 75 years with infrequent viral epidemics (5–9 year cycles) and no feral populations of pea have been recorded; therefore environmental and cultural conditions are the more likely agent preventing establishment of feral populations'' (Ref. 42). EPA therefore believes that pea meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

v. *Peanut*. EPA proposes that peanut (*Arachis hypogaea*) be included on the list in § 174.27(a)(1) based on EPA consultations with peanut experts. These consultations indicate that peanut meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make peanut weedy or invasive. All three experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''virus pressure is not the limiting factor. Even without virus pressure peanut (Arachis hypogaea) are not able to become feral or easily spread into non-crop areas. Peanut are not able to sustain long term natural populations without cultivation by man'' (Ref. 42). EPA therefore believes that peanut meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

w. *Pineapple*. EPA proposes that pineapple (*Ananas comosus*) be included on the list in § 174.27(a)(1) based on EPA consultations with pineapple experts. These consultations indicate that pineapple meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert indicated, ''The taxonomy of the genus Ananas was recently critically reviewed and revised (Chan et al., 2003) and all of the wild relatives of pineapple are classified in the same genus and species as the cultivated pineapple but are different botanical varieties. These are Ananas comosus var. ananassoides and A. comosus var. parguazensis (Chan et al., 2003). If these wild relatives are found in the United States and its territories they would be in cultivated gardens or in pots. There are no reports that A. comosus var comosus or its wild relatives survive naturally in the wild or pose a potential threat as weed species. If natural crosses between Ananas species occur in nature, it is highly unlikely that seed produced from them would survive to produce a mature plant'' (Refs. 42 and 47). Second, the experts agreed that pineapple is not currently weedy or invasive in the United States. Third, these experts agreed that it is unlikely that acquisition of virus resistance would make pineapple weedy or invasive. For example, one expert stated, ''Assuming transgenic plants were resistant to all known pests, pineapple still cannot compete with weeds, which quickly overtop slower growing pineapple plants. Pineapple lacks any natural mechanism for vegetative propagation and does not propagate naturally by seeds because seedlings are delicate and require special care to survive to maturity'' (Ref. 42). EPA therefore believes that pineapple meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

x. *Potato*. EPA proposes that potato (*Solanum tuberosum*) be included on the list in § 174.27(a)(1) based on the Agency's experience regulating PIPs in potato (Ref. 44), literature that is available on potato biology, the OECD Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (Ref. 48), and EPA consultations with potato experts (Ref. 42). This body of information indicates that potato is low risk with respect to concerns associated with weediness.

EPA's 2001 risk assessment for Bt PIPs evaluated the potential for potato to form viable hybrids with wild or weedy relatives in the United States (Ref. 44). EPA's conclusion was that there is no foreseeable risk of gene capture and PIP expression in wild relatives of *Solanum tuberosum* in the United States. Successful gene introgression into tuber-bearing *Solanum* species is virtually excluded due to constraints of geographical isolation and other biological barriers to natural hybridization (Ref. 49). These barriers include incompatible (unequal) endosperm balance numbers that lead to endosperm failure and embryo abortion, multiple ploidy levels, and incompatibility mechanisms that do not express reciprocal genes to allow fertilization to proceed. No natural hybrids have been observed between these species and cultivated potatoes in the United States.

The body of information EPA consulted on potato also indicates that the crop is not currently weedy or invasive in the United States. According to the OECD consensus document, ''[o]utside the field, potato seedlings will have difficulty establishing themselves as they cannot compete with other plants. Love et al., 1994 report that these seedlings are limited to cultivated areas for reasons of competition and adaptation. Potato tubers can be spread during transportation and use, but generally these plants will not be established for a long time due to unfavourable environmental conditions. In general, the potato is not known as a coloniser of unmanaged ecosystems'' (Ref. 48). One expert EPA consulted indicated potato ''is a rare weed in potato plots but it never becomes feral in the United States'' (Ref. 42).

Finally, there is no reason to believe that acquisition of virus resistance would make potato weedy or invasive, as viruses are not consistently associated with failure of potato to show any evidence of being weedy or invasive. The experts that EPA consulted agree that it is not very likely that potato would become feral or easily spread into non-crop areas if it acquired transgenic virus resistance. For example, one expert consulted indicated that ''[t]he basis of poor survival of cultivars in natural habitats is not due to virus susceptibility'' (Ref. 42). EPA therefore believes that potato meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

y. *Soybean*. EPA proposes that soybean (*Glycine max*) be included on the list in § 174.27(a)(1) based on literature that is available on soybean biology, the OECD Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean) (Ref. 50), and EPA consultations with soybean experts. This body of information indicates that soybean meets the three conditions outlined above by the SAP: It does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make soybean weedy or invasive, as viruses are not consistently associated with failure of soybean to show any evidence of being weedy or invasive. All four experts contacted by EPA indicated agreement with these statements. For example, one expert stated, ''Acquiring transgenic virus resistance will not change the ability of soybean to become feral since it will still be a domesticated species and does not have the attributes to

survive without human intervention. Virus diseases in the U.S. do not generally cause major yield loses [sic] and resistance to some viruses is very common in soybean. Transgenic virus resistance will not substantially change how the soybean interacts with most environments'' (Ref. 42). According to the OECD consensus document, ''[t]he soybean plant is not weedy in character. In North America, *Glycine max* is not found outside of cultivation. In managed ecosystems, soybean does not effectively compete with other cultivated plants or primary colonizers'' (Ref. 50). EPA therefore believes that soybean meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

z. *Starfruit*. EPA proposes that starfruit (*Averrhoa carambola*) be included on the list in § 174.27(a)(1) based on EPA consultations with starfruit experts. These consultations indicate that starfruit meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. One expert mentioned that starfruit can hybridize with wild *Averrhoa carambola*, but another expert indicated that researchers have concluded wild starfruit trees can no longer be found in the United States (Ref. 42). Second, these experts agreed that starfruit is not currently weedy or invasive in the United States. Third, these experts agreed that it is unlikely that acquisition of virus resistance would make starfruit weedy or invasive. For example, one expert stated, ''It is highly unlikely that starfruit with acquired transgenic resistance would spread to non-crop areas because... seed recalcitrance in starfruit... results in a loss of viability shortly after harvest'' (Ref. 42). EPA therefore believes that starfruit meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

aa. *Sugarcane*. EPA proposes that sugarcane (*Saccharum officinarum*) be included on the list in § 174.27(a)(1) based on EPA consultations with sugarcane experts. These consultations indicate that sugarcane meets the three conditions outlined above by the SAP. One, it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature. According to one expert, ''Although in theory it should happen in more tropical regions of the world, hybrid seedlings among commercial or wild relatives are not observed. Breeders routinely generate hybrids among commercial sugarcane (derived from interspecific hybrids of *Saccarhum* [sic] *officinarum* and *S. sponteneum*), and among commercial and wild relatives (*S. spontaneum* mostly) under controlled conditions of heating and photoperiod control. The resulting progeny are quite weak and must be husbanded under greenhouse-type conditions prior to planting in the field'' (Ref. 42). Second, these experts agreed that sugarcane is not currently weedy or invasive in the United States. One expert stated, ''Commercial sugarcane is clonally propagated. Occasionally some of the harvested cane may be lost from the trucks or wagons while in transport from the field to the processing factory. If the cane has not been burned prior to harvest, volunteer plants occasionally grow along the transport route. This cane is not sexually reproducing, nor is it invasive in nature. Simple roadside mowing or natural weather conditions usually eliminate it'' (Ref. 42). Third, these experts agreed that it is unlikely that acquisition of virus resistance would make sugarcane weedy or invasive. For example, one expert stated, ''commercial sugar does not become a feral pest under regular commercial production conditions. The majority of existing commercial cultivars have been bred for genetic resistance to various disease-causing sugarcane viruses. None of these cultivars have become feral or a pest in anyway [sic]'' (Ref. 42). EPA therefore believes that sugarcane meets the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

bb. *Tulips*. EPA proposes that tulips (*Tulipa* spp.) be included on the list in § 174.27(a)(1) based on EPA consultations with tulip experts. These consultations indicate that tulips meet the three conditions outlined above by the SAP. One, they do not have wild or weedy relatives in the United States with which they can form viable hybrids in nature. Two, they are not currently weedy or invasive in the United States, although two experts indicated that *Tulipa sylvestris* naturalizes in certain areas without being viewed as a significant problem because it reproduces only vegetatively. Three, there is no reason to believe that acquisition of virus resistance would make tulips weedy or invasive. One expert noted that this was ''possible, but unlikely. Virus resistance could conceivably increase the vigor of the vegetative spread of *T. sylvestris*'' (Ref. 42). However, three other experts believed that this was highly unlikely to occur. One said, ''The need for chilling in this genus means that it is restricted to temperate areas with summer-cool climates. Areas where it can persist are very limited and there is a high degree of browsing of this genus by vertebrates such as deer that make seed production in the wild a very rare occurrence in nature in the U.S.'' (Ref. 42). EPA therefore believes that tulips meet the conditions recommended by the 2005 SAP for inclusion on the list and will present low risk with respect to weediness.

ii. *Adding plants to the categorical exemption criterion in § 174.27(a)(1)*. As the Agency gains additional experience, it may propose to add crops to the list. In addition, any person may petition the Agency to add particular crops to the list. EPA would evaluate any potential candidates against the same considerations used in this rulemaking to develop the list in § 174.27(a)(1) discussed above. Consequently, for a petition to be successful, it should contain sufficient data or other information to allow EPA to perform such an analysis, e.g., published information or a consensus opinion among experts in the particular crop that addresses the questions EPA posed in its expert consultations (discussed in Unit III.C.2.i.). Petitioners are welcome to consult with EPA prior to preparing a submission to discuss the information that would be required. EPA would consult with USDA in evaluating petitions for adding plants to § 174.27(a)(1).

Any subsequent addition of crops to the list in § 174.27(a)(1), either through the Agency's own initiative or in response to a petition from the public, may only occur through rulemaking. Under FIFRA section 25, rulemaking involves several steps, including reviews by the SAP and USDA. In general, EPA would seek to expedite the process and proceed through direct final rulemaking where feasible. Under such a process, in cases where EPA believes that the proposal will not raise scientifically complicated issues, EPA would simultaneously issue a final rule and a proposal. If no adverse comments were received, the final rule would go into effect and EPA would withdraw the proposed rule. In the event of adverse comment, EPA would withdraw the final rule and would proceed to issue a final rule that addressed the public comments received on the proposal. In addition, as part of this current rulemaking, because EPA's analysis to determine whether to add a crop to the list would be consistent with the criteria provided by the SAP, the Agency would request that the SAP generally waive its

review of subsequent rules seeking to add further crops to the list in § 174.27(a)(1) unless EPA subsequently determines that a particular rule raised novel or particularly complex scientific issues.

iii. *Proposed exemption criterion conditional on Agency determination in § 174.27(a)(2).* EPA recognizes that many PVCP-PIP/plant combinations would reasonably be expected to pose low risk with respect to weediness even though the crop plant containing the PVCP-PIP is not on the Agency's proposed list in § 174.27(a)(1). EPA has not conducted an exhaustive survey of all crop plants to evaluate them for inclusion on this list and therefore recognizes that additional plants may meet the conditions that were used to compile this list of plants. Therefore, in addition to the categorical exemption criterion, EPA also believes that a criterion conditional on Agency determination could be developed that would identify plants that are low risk with respect to weediness.

EPA is considering four options for such a conditional exemption criterion under which PVCP-PIP/plant combinations that fail to meet § 174.27(a)(1) could still meet § 174.27(a) under § 174.27(a)(2), subject to an Agency review. Each of the options reflects a somewhat different approach to implementing the recommendations of the 2005 SAP (Ref. 11). EPA does not currently have a preferred approach and presents several options to promote full consideration of the issues, although option 1 is presented in the regulatory text so the public could see how § 174.27(a)(2) might fit into the overall framework of the exemption.

a. *Option 1.* The first option for § 174.27(a)(2) provides the strictest interpretation of the 2005 SAP advice. Under this option, a PVCP-PIP would meet § 174.27(a) under § 174.27(a)(2) if the Agency determines after review that the plant containing the PIP meets all of the following:

(i) Has no wild or weedy relatives in the United States with which it can form viable hybrids in nature.

(ii) Is not a weedy or invasive species outside of agricultural fields in the United States.

(iii) Is unlikely to establish weedy or invasive populations outside of agricultural fields in the United States even if the plant contains a PVCP-PIP.

EPA would expect exemption submissions to document that the plant meets these conditions in the opinion of agronomists, breeders, ecologists, and other experts working with the specific taxa in question or based on data. When these conditions are met, the likelihood that a PVCP-PIP could cause increased weediness of any plant would be very small, as discussed in the following paragraphs.

If the plant containing the PVCP-PIP has no wild or weedy relatives in the United States with which it can form viable hybrids in nature and thus would meet the criterion in § 174.27(a)(2)(i) under option 1, it would not be possible for the PVCP-PIP to inadvertently be transferred to any wild or weedy relatives, e.g., through pollen flow. Whether the recipient plant ''can produce viable hybrids in nature'' is a critical attribute that would definitively determine the potential for introgression of the PVCP-PIP into a native or naturalized plant population. Although hybrids must be able to reproduce themselves in order for introgression to occur, the production of ''viable'' hybrids (i.e., those that are able to grow) may be described more clearly in a regulatory standard than examining the reproductive potential of any hybrids. In many cases, reproductive potential of hybrids has not been fully investigated. Given that reduced fertility in F1 crop-wild hybrids is frequently restored to normal in subsequent generations (Ref. 37), measurement of hybrid fertility involves consideration of several generations. In addition, viability is a more reliable standard because even very low rates of gene transfer could lead to introgression (Ref. 51), suggesting that any degree of hybrid fertility could indicate the potential for introgression to occur. As noted by the 2005 SAP, ''it is known that favorable alleles (including, perhaps, a PVCP-PIP) can pass easily from one species to another through hybrid zones, even when the hybrids have very low fitness (Barton 1986)'' (Refs. 11 and 52). The Agency recognizes that introgression of a trait such as virus resistance into natural plant populations does not automatically confer a competitive advantage to the recipient population. However, at this time, there is little information available to predict categorically whether acquisition of such a trait might affect the competitiveness of a specific plant population, and the available information does not allow the Agency to make this determination *a priori*. The ability to produce viable hybrids is relatively easy to evaluate, resulting in a clear criterion that ensures an effective limitation on the potential for introgression. Such language also clarifies that the relevant question is whether the hybrid can be produced ''in nature.'' The fact that plants could be crossed in the laboratory or greenhouse is not necessarily indicative of a plant's true reproductive potential. The Agency's focus is whether a viable hybrid could be produced under normal growing conditions in the field or in nature, rather than under controlled experimental conditions that might have little relevance to behavior in the environment.

If the plant containing the PVCP-PIP is not a weedy or invasive species outside of agricultural fields in the United States and thus would meet the criterion in § 174.27(a)(2)(ii) under option 1, established and persistent feral populations of the crop presenting difficult management issues in natural or semi-managed ecosystems would be unlikely. Thus, transfer of the PVCP-PIP from the crop to a feral population would be unlikely to exacerbate what could already be a difficult problem by inadvertently increasing the population's weediness potential. EPA proposes inclusion of the term ''outside of agricultural fields'' to emphasize that the key consideration is the plant's behavior in natural settings, including semi-managed habitat surrounding agricultural fields as opposed to its behavior within the fields themselves. EPA recognizes that most crops within agricultural fields form volunteer populations, where propagules of the crop from the previous rotation grow in the subsequent crop rotation. The Agency believes the language ''outside of agricultural fields'' appropriately excludes this situation from consideration.

If the plant containing the PVCP-PIP is unlikely to establish weedy or invasive populations outside of agricultural fields in the United States even if the plant contains a PVCP-PIP and thus would meet the criterion in § 174.27(a)(2)(iii) under option 1, an additional level of assurance would be provided that the crop plant would not present weediness concerns through acquisition of a PVCP-PIP. EPA believes that this condition could in general be met based on the opinion of experts on the particular crop. Experts may judge, for example, that acquisition of virus resistance is unlikely to change the weedy or invasive characteristics of the plant if the crop does not appear to be weedy or invasive when virus infection is known to be absent from a particular area or over a particular period of time. Available empirical data could be used in the determination or may be gathered if expert opinion cannot resolve the question.

EPA proposes to define the term ''weedy species'' used in § 174.27(a)(2)(ii) to mean ''a species that

is an aggressive competitor in natural ecosystems.'' EPA intends to use the term ''invasive species'' consistent with the definition in Executive Order 13112, meaning an alien species whose introduction causes or is likely to cause economic or environmental harm or harm to human health. An alien species means, with respect to a particular ecosystem, any species, including its seeds, eggs, spores, or other biological material capable of propagating that species, that is not native to that ecosystem. EPA uses the phrase ''weedy or invasive populations'' in § 174.27(a)(2)(iii) consistent with these definitions.

EPA notes that the criterion in § 174.27(a)(2)(i) under option 1 does not necessarily strictly hold for every crop that appears on the list in proposed § 174.27(a)(1). In some cases, EPA was able to make a low risk determination for a particular crop, e.g., corn, in spite of the possible presence of wild or weedy relatives in the United States with which the plant may in rare cases form viable hybrids in nature. EPA has presented the basis for such conclusions in this proposed rule, and the public can clearly understand why the crops in § 174.27(a)(1) meet the Agency's low risk standard with respect to weediness concerns. Given that several crops for which EPA has made a low risk determination and proposes to include in § 174.27(a)(1) would not meet § 174.27(a)(2) as proposed under option 1, EPA believes that option 1 may be too narrow. Accordingly, EPA is considering other options for § 174.27(a)(2) that are based on a less literal interpretation of the SAP's recommendations but which the Agency believes are nevertheless consistent with the SAP's intent.

b. *Option 2*. The second option EPA is considering is that a PVCP-PIP would meet the criterion in § 174.27(a)(2)(i) if ''the plant containing the PIP has no wild or weedy relatives in the United States with which it can form viable, *fertile* hybrids in nature, or if fertile, the resulting hybrid cannot establish populations in the environment.'' EPA is considering this option because most crops are able to form viable hybrids with a wild or weedy relative in some part of the United States. However, some viable, fertile hybrids may nevertheless present low risk with respect to concerns associated with weediness, e.g., if the hybrids are weak and lack the ability to establish. On the other hand, fertility and the potential to establish are more difficult characteristics to evaluate than viability because many more variables affect the determination, suggesting that it might be more appropriate in these cases for the Agency to require that data be collected for a period of time after commercial deployment that could confirm the Agency's original analysis. However, while such conditions may be readily placed on a PVCP-PIP registration, they could not be placed on an exempt PVCP-PIP. In addition, determinations under option 2 would be more difficult for the public to predict than determinations under option 1, as discussed in Unit III.A.2.

c. *Option 3*. Under the third option being considered, EPA would adopt only the criteria in § 174.27(a)(2)(i) and (a)(2)(ii) as discussed above under option 1. The rationale for such an approach is that it may not be necessary to evaluate the criterion in § 174.27(a)(2)(iii) in order to make a low risk determination because the issues are adequately addressed by the other two criteria. Viruses generally do not uniformly affect crops every season in every place they are planted - even those crops that viruses significantly impact such that development of a PVCP-PIP to combat the disease might be undertaken. Crops will thus have repeated opportunity to escape cultivation in seasons and in areas where there is no virus infestation. If weedy tendencies are rarely or never observed in any part of the crop's range, it is unlikely that virus resistance affects the crop's ability to escape cultivation and establish weedy populations. Unlike wild or weedy plant relatives that may at times be infected by viruses and may be negatively impacted by viruses in ways that are not obvious to untrained observers, breeders and farmers are intimately aware of the type of damage done by virus infection to crops and are therefore well aware when their fields are or are not infected. Crop plants have been observed under a diverse range of environmental conditions over many years. If a PVCP-PIP were likely to make a crop weedy or invasive, such tendencies would likely have been observed even without virus resistance at some point in time given the level of observation crops generally receive due to the necessity to actively manage their cultivation. Such crops showing weedy or invasive tendencies would not meet the criterion in § 174.27(a)(2)(ii), suggesting that the criterion in § 174.27(a)(2)(iii) is largely redundant with this condition.

EPA notes that option 3 is likely to be equally as narrow as options 1 and 2. The advantage of the option would be a simplification of the issues that a PVCP-PIP developer would need to address as part of a submission for an exemption determination.

EPA could consider factors that are not considered under options 1–3 but that would affect the potential impact of PVCP-PIP acquisition as part of evaluating a PVCP-PIP for FIFRA registration. For example, EPA could take into account the effect of virus infection on such species, the existence and impact of any natural virus resistance in the population, the overlap of the plant's distribution with crop cultivation areas, and other relevant considerations.

d. *Option 4*. The fourth option EPA is considering is that a PVCP-PIP would meet § 174.27(a)(2) if the Agency determines that ''the PVCP-PIP is unlikely to significantly change the population size or distribution of the species containing the PVCP-PIP outside of agricultural fields or the population size or distribution of any wild or weedy species in the United States that could acquire the PVCP-PIP through gene transfer.'' EPA is considering this fourth option because the Agency recognizes that many PVCP-PIPs excluded from exemption under the criterion in § 174.27(a)(2)(i) of options 1–3 because of wild or weedy relatives in the United States may nevertheless present low risk. The presence of wild or weedy relatives relates only to potential exposure of the PVCP-PIP and does not indicate whether the PVCP-PIP is likely to cause any adverse effects even if it were to transfer to these relatives. EPA believes that such an evaluation would be consistent with the advice of the 2005 SAP, which noted that ''[t]he probability that a particular transgene will lead to increased weediness depends on the phenotype conferred by the transgene and on the ecological factor(s) currently limiting the size or distribution of the wild species. In particular, if the transgene alters plant response to an ecological factor limiting population size, then population dynamics may be affected. For PVCP-PIPs, the relevant consideration is whether virus resistance (conferred by the PVCP-PIP) leads to changes in the size or distribution of wild plant species with the PVCP-PIP'' (Ref. 11).

With option 4, EPA would conduct a risk assessment to evaluate a clear end point - whether there is likely to be a significant change in the population size or distribution of the species containing the PVCP-PIP outside of agricultural fields or the population size or distribution of any wild or weedy species in the United States that could acquire the PVCP-PIP through gene transfer. However, for the vast majority of species, many characteristics that would influence this determination are

currently poorly understood, e.g., the impact of virus infection on wild plant populations and the likely selective advantage afforded by acquisition of virus resistance. As a result, both the nature of EPA's evaluation and the type and extent of data that might need to be provided to the Agency resemble much more closely what would be required to evaluate weediness issues during a FIFRA registration review. In addition, the more the exemption determination process resembles a full risk assessment, the longer the time required for EPA to complete such a review.

Although EPA would seek public comment on determinations that a PVCP-PIP met § 174.27(a)(2) according to the procedure for exemptions utilizing any Agency-determined criteria, Agency determinations may be more controversial with this option than with other options that have more clearly defined criteria. EPA believes that case-by-case determinations could be made appropriately and that the data requirements needed to evaluate the criterion under option 4 would not necessarily be overly burdensome. EPA notes that in many cases much of the data, if not all, needed for EPA to evaluate a criterion such as this fourth option would also be needed for a petition for determination of nonregulated status submitted to USDA. EPA believes that the flexibility of this option will make it more likely that the Agency would identify the largest number of low risk products that could qualify for exemption.

For all options for proposed § 174.27(a)(2), the Agency believes the entire United States is the relevant scope of inquiry because the proposed exemption would carry no limitations on where the exempted PVCP-PIP/plant combination could be planted and thus could be planted in all areas subject to U.S. law. FIFRA section 2(aa) defines ''State'' as ''a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa. Accordingly, the term ''United States'' used in this proposal includes all these areas, and EPA proposes to incorporate a definition of ''United States'' paralleling the FIFRA definition of ''State'' into the definitions in 40 CFR 174.3.

As an alternative to Agency review pursuant to § 174.27(a)(2), a developer could petition EPA to add a crop to the list in § 174.27(a)(1). In some cases, EPA expects that the same data/information that would support a determination that a crop meets § 174.27(a)(2) would support listing the crop in § 174.27(a)(1). However, because a plant can only be added to the list in § 174.27(a)(1) through rulemaking, EPA expects that many developers will instead prefer to obtain an Agency determination under § 174.27(a)(2). However, once a plant is added to the list in § 174.27(a)(1), future PVCP-PIPs used in that plant would meet § 174.27(a) without any Agency review.

3. *Historical approaches*. In 1994 EPA proposed two different alternatives for exempting PVCP-PIPs from FIFRA requirements. The Agency prefers the approaches discussed in the preceding Subunit because they have been developed based on recent interactions with the SAP and thus represent the most current science. One 1994 alternative contained exemption criteria directed towards addressing concerns associated with gene transfer to identify those PVCP-PIP/plant combinations with the lowest potential to confer selective advantage on wild or weedy plant relatives. EPA described this alternative exemption as follows:

> Coat proteins from plant viruses [would be exempt] if the genetic material necessary to produce a coat protein is introduced into a plant's genome and the plant has at least one of the following characteristics:
>
> (1) The plant has no wild relatives in the United States with which it can successfully exchange genetic material, i.e., corn, tomato, potato, soybean, or any other plant species that EPA has determined has no sexually compatible wild relatives in the United States.
>
> (2) It has been demonstrated to EPA that the plant is incapable of successful genetic exchange with any existing wild relatives (e.g., through male sterility, self-pollination).
>
> (3) If the plant can successfully exchange genetic material with wild relatives, it has been empirically demonstrated to EPA that existing wild relatives are resistant or tolerant to the virus from which the coat protein is derived or that no selective pressure is exerted by the virus in natural populations (59 FR 60504, November 23, 1994).

EPA carefully reconsidered this 1994 proposal in its deliberations for today's proposed exemption and presented these criteria in modified form to the FIFRA SAP at the October 2004 and December 2005 meetings for consideration. In light of comments received from the FIFRA SAP and additional scientific information available since 1994, EPA no longer believes this alternative would adequately address questions associated with weediness in a manner that could be reasonably implemented. However, EPA still considers that it would be appropriate to limit the exemption based on the concerns outlined in the earlier proposal associated with acquisition of virus resistance through hybridization with a transgenic plant containing a PVCP-PIP.

Although similar in intent to characteristic (1) of this option proposed in 1994, today's proposed criterion in § 174.27(a)(2)(i) under option 1 focuses in part on the potential to ''form viable hybrids in nature'' rather than simply ''exchange genetic material'' because the former is a clearer standard for determining whether a PVCP-PIP could have the potential to affect a recipient plant population negatively. The ability to exchange genetic material, which is often demonstrated by performing hand crosses in the laboratory or greenhouse, may not indicate any relevant information about how the plants would behave in nature. Today's proposed criterion in § 174.27(a)(1) also uses a somewhat different list of plants than the four in the 1994 proposal. Several species have been added (see Unit III.C.2.i.) and tomato has been removed from the list because of information acquired through expert consultation. (See Unit VII for a discussion of this information and to read EPA's request for comment). When EPA presented a criterion similar to the first characteristic in the 1994 proposal to the 2004 SAP, they responded that ''the Panel was of the opinion that the absence of a competent wild/weedy relative positioned in relation to the plant containing the PVCP-PIP was an appropriate condition.'' The 2005 SAP also ''was supportive of the Agency's intent to exempt from regulation any PVCP-PIP crops that (1) do not have sexually compatible wild relatives in the location of intended cultivation (US & Territories) and (2) are not likely to become weedy themselves'' (Ref. 11).

EPA now also believes that characteristic (2) of the option proposed in 1994 may be insufficient based on the conclusions of the 2004 SAP and the National Research Council that current methods of bioconfinement are imperfect and are unlikely to adequately restrict gene flow (Refs. 25 and 53). The Agency asked the 2004 SAP whether the condition that ''genetic exchange between the plant into which the PVCP-PIP has been inserted and any existing wild or weedy relatives is substantially reduced by modifying the plant with a scientifically documented method, (e.g., through male sterility)'' would be necessary and/or sufficient to minimize the potential for a PVCP-PIP to harm the environment through gene transfer from the crop plant containing the PVCP-PIP to wild or weedy relatives. The Panel ''accepted that tactics aiming at diminished gene exchange are highly desirable and even necessary but are not sufficient'' (Ref. 25).

In spite of such concerns, EPA is still considering whether a criterion involving biocontainment could be sufficient to enable the Agency to determine with review that a product presents low risk with respect to concerns associated with weediness. The 2005 SAP concluded ''that if highly effective biological containment and biological mitigation methods could be deployed concurrently with the PVCP-PIP, then it would be possible to exempt crops with sexually compatible wild relatives. This opinion is different from the opinion of the October 2004 FIFRA SAP. The [2005] Panel concluded that this difference is probably due to advances in containment and mitigation strategies. For this reason, exemptions might be granted to any crop that hybridizes with a wild relative in the US, its possessions or territories, if the F_1 and BC (backcross) hybrids have very low fitness such that it is effectively lethal. Additionally, an exemption might be possible if specific genes for lowering fitness are in tandem constructs with the PVCP-PIP gene in such a way that they cannot readily segregate from each other. The Panel did not determine what level of effectiveness would be required but, it was agreed that stacked strategies would reduce the cumulative risk, and should be strongly considered'' (Ref. 11).

Bioconfinement strategies are known to have a wide range of efficacy, and no standard level of efficacy to ensure environmental safety has been determined (Ref. 53). Additionally, some techniques may introduce risk concerns that must be evaluated, e.g., unintended impacts on wildlife that eat seeds or pollen (Ref. 25). However, scientific advancements may make bioconfinement techniques sufficiently reliable and safe in the future such that deployment with a PVCP-PIP would be sufficient to reach a low risk finding with respect to concerns associated with weediness (Refs. 54 and 55). Therefore, EPA is still considering a condition such as characteristic (2) proposed in 1994 that would constitute an alternative way to meet § 174.27(a)(2) under any of the options discussed in this Preamble. For example, § 174.27(a)(2) might read:

The Agency determines after review that the plant containing the PIP:

(i) Has no wild or weedy relatives in the United States with which it can form viable hybrids in nature or employs a highly effective biological containment technique.

(ii) Is not a weedy or invasive species outside of agricultural fields in the United States or employs a highly effect biomitigation construct that ensures escapes from cultivation are too unfit to compete with wild-types.

EPA believes that characteristic (3) of the option proposed in 1994 is sound conceptually. However, the Agency's intent in developing this exemption has historically been to have criteria that identify low risk PVCP-PIPs such that the criteria could be evaluated with information that a developer is likely to have acquired in the course of developing the product and not require significant data generation. The Agency presented a similar criterion to the 2004 SAP for their consideration: ''all existing wild or weedy relatives in the United States with which the plant can produce a viable hybrid are tolerant or resistant to the virus from which the coat protein is derived.'' The Panel members suggested that such a criterion would be difficult to implement in a clear and transparent exemption review process given that ''[t]he Panel had particular difficulty when attempting to add precision to approaches that should be followed when sampling wild and weedy relatives for the occurrence of specific virus tolerance or resistance as specified by the Agency.''

As an alternative to a criterion like that described by characteristic (3) in the 1994 proposal whose evaluation would necessitate collection of potentially significant amounts of data, EPA presented another option to the 2005 SAP: ''(i) the plant containing the PVCP-PIP is itself not a weedy or invasive species outside of agricultural fields in the United States, its possessions, or territories, and (ii) the plant containing the PVCP-PIP does not have relatives outside of agricultural fields in the United States, its possessions, or territories that are weedy or invasive species or endangered/threatened species with which it can produce viable hybrids in nature'' (Ref. 11). However, the Panel concluded that ''the probability that a particular transgene alters the dynamics of a wild relative cannot be predicted by the current status of the wild species as weedy, invasive, or threatened/endangered. The Panel agreed that the criteria proposed by the Agency would not correctly identify PVCP-PIPs which pose unacceptable environmental risks'' (Ref. 11). EPA has therefore concluded that the Agency is unable at this time to articulate a clear criterion for exemption that would expand the eligible plants beyond those roughly described by the ideas in the 1994 characteristic (1) unless the Agency were to adopt a criterion whose evaluation involved conducting a risk assessment of the PVCP-PIP/plant combination such as it put forth in this preamble as the fourth option for proposed § 174.27(a)(2), i.e., that the PVCP-PIP is unlikely to significantly change the population size or distribution of the species containing the PVCP-PIP outside of agricultural fields or the population size or distribution of any wild or weedy species in the United States that could acquire the PVCP-PIP through gene transfer (discussed in Unit III.C.2.iii.d.).

The other alternative proposed in 1994 did not contain a criterion addressing concerns associated with gene flow. This option proposed a full categorical exemption for all PVCP-PIPs (59 FR 60503). This option is no longer the Agency's preferred approach for a number of reasons. Specifically, EPA has received scientific advice since issuance of the 1994 proposal calling into question the Agency's 1994 rationale that all PVCP-PIPs meet the FIFRA 25(b)(2) exemption standard, including gene flow considerations. Although EPA believes that many PVCP-PIPs present low risk and thus meet the FIFRA 25(b)(2) exemption standard, in order to categorically exempt all PVCP-PIPs, the Agency must be able to draw this conclusion for all PVCP-PIPs. Advances in scientific understanding since 1994 suggest it may not be possible to support this rationale for all PVCP-PIPs and that certain PVCP-PIPs may pose a greater level of risk than is characteristic of the group as a whole. For example, virus resistance is common in natural plant populations as evidenced by conventionally bred virus resistant plants that are only possible due to naturally existing resistance in crop and wild relative populations (Ref. 20). This fact suggests that acquisition of virus resistance is often unlikely to introduce a novel trait into many plant populations. However, some notable exceptions to the ubiquity of virus resistance in natural plant populations exist including the lack of successful conventionally bred resistance to barley yellow dwarf virus in major crops and the lack of natural resistance in some wild relatives of these crops (Ref. 36). Such information suggests that acquisition of a PVCP-PIP by such wild relatives of these plants has the potential to free these wild relatives from what may be an important ecological constraint. The conclusions of the 2004 FIFRA SAP are consistent with the idea that it may not be possible to apply a general exemption rationale to all PVCP-PIPs. The report concluded that ''...PVCP-PIPs [have] no inherent capacity to harm the environment.'' However, ''[i]t was recognized that knowledge of hybridization potential was sparse and of very unequal quality but the likelihood of serious economic

harm was such that some plants engineered to contain stress tolerant traits should not be released'' (Ref. 25). The 2005 SAP's conclusions discussed above also clearly suggest that crops containing a PVCP-PIP that have wild relatives must be carefully considered on a case-by-case basis (Ref. 11). Similarly, the 2000 National Research Council (NRC) report recommended that because of concerns associated with hybridization with weedy relatives, ''EPA should not categorically exempt viral coat proteins from regulation under FIFRA. Rather, EPA should adopt an approach, such as the agency's alternative proposal..., that allows the agency to consider the gene transfer risks associated with the introduction of viral coat proteins to plants'' (Ref. 10).

D. Viral Interactions

1. *Scientific issues*. In addition to weediness, a key issue associated with PVCP-PIPs is the question of whether they could affect the epidemiology and pathogenicity of plant viruses. Given the potential impact of virus infection, such changes might affect competitiveness of plant populations thereby altering ecosystem dynamics, e.g., through significant changes in species composition of populations, resource utilization, or herbivory.

The genetic material of plant viruses may be composed of either RNA or DNA, although most have RNA genomes (Ref. 56). Although there are significant differences between RNA and DNA viruses, both are obligate parasites that usually move from plant to plant via vector-mediated transmission. Such transmission, in connection with other types of virus transmission, commonly leads to mixed viral infections in crops and other plants (Ref. 57). In natural, mixed infections, viral genomes from different strains and/or different species simultaneously infect the same plant and thus have opportunities to interact (e.g., through recombination, heterologous encapsidation, or synergy). In spite of many opportunities for interaction in nature, such events rarely lead to any detectable adverse outcome (Ref. 58). However, such *in planta* interactions have the potential to result in a virus that causes increased agricultural or other environmental damage.

In transgenic plants containing PVCP-PIPs, every virus infection can be considered in one sense to be a mixed infection with respect to the coat protein gene (Ref. 59). The key questions facing EPA are whether interactions between such introduced plant virus sequences and infecting viruses in transgenic plants may increase in frequency or be unlike those expected to occur in nature (Ref. 60). The Agency has written a literature review addressing these questions (Ref. 60) and will briefly describe the issues associated with recombination, heterologous encapsidation, and synergy below. EPA provides a general overview of each of the processes separately, followed by a brief review of relevant field studies that investigated these processes.

i. *Recombination*. Recombination is a natural process that can occur during replication of DNA or RNA whereby new combinations of genes are produced. Plant virus recombination can occur between members of the same virus pathotype in natural infections, contributing to the number of variants that exist within that pathotype. Recombination can also occur when different viruses coinfect the same plant and interact during replication to generate virus progeny that have genetic material from each of the different parental genomes. Although recombination likely occurs regularly in mixed viral infections, recombination only rarely leads to viable viruses and even more rarely to viruses with truly novel behavior and/or characteristics or any detectable adverse outcome. In order to persist in nature, a recombinant virus must be competitive with variants of the parental viruses that have already demonstrated success in all stages of the infective cycle, e.g., transmission, gene expression, replication, and assembly of new virions (Ref. 58). An analysis of cucumber mosaic virus (CMV) isolates in natural populations showed that viable recombinants were very rarely recovered in mixed infections (Ref. 61).

Although selection in the field appears to act against persistence of new, recombinant viruses, recombination is thought to play a significant role in virus evolution, presumably because recombinant viruses are on very rare occasions able to outcompete existing viruses. How a virus with increased pathogenicity or altered epidemiology might conceivably be created through recombination was suggested by a laboratory experiment in which a pseudorecombinant strain was created by experimentally combining regions of the CMV and tomato aspermy virus (TAV) genomes. This artificially manipulated virus was found to cause more severe symptoms than either of the parental genomes, although the recombinant was not a fully-functional virus as it was not able to move beyond the initially infected cells (Ref. 62) and would therefore not be expected to persist in nature. Another laboratory experiment has shown interspecific recombination between CMV and TAV under conditions in which recombinants would not be expected to have any particular fitness advantage (Ref. 63). In another example, alteration of the host range of tobacco mosaic virus (TMV) occurred when a chimeric virus expressed the coat protein from alfalfa mosaic virus (AMV) instead of its own (Ref. 64).

Evidence of past recombination having led to the creation of new RNA viruses has been documented in a number of different groups including bromoviruses (Ref. 65), luteoviruses (Ref. 66), nepoviruses (Ref. 67), and cucumoviruses (Ref. 68). Sequence analysis of viruses from the family *Luteoviridae* indicated that this family has evolved via both intra- and interfamilial recombination (Ref. 69). Interspecific recombination between two related potyviruses, soybean mosaic virus (SMV) and bean common mosaic virus (BCMV) apparently led to the creation of watermelon mosaic virus (WMV) with a broader host range than either SMV or BCMV (Ref. 70). Whereas these latter two viruses are generally restricted to *Leguminosae*, WMV has one of the broadest host ranges among the potyviruses being able to infect both monocots and dicots. For RNA viruses, evidence of recombinant viruses arising in recent history has not been reported, suggesting that recombination as a factor in RNA virus evolution may generally only be significant over a longer timescale.

Recombination has also played a role in the evolution of new DNA viruses including caulimoviruses (Ref. 71) and geminiviruses (Refs. 72 and 73). For DNA viruses, geminiviruses in particular, several instances can also be cited in which relatively recent recombination events appear to have resulted in the creation of new viruses. For example, a recent epidemic of severe cassava mosaic disease in Uganda is thought to be due to the combination and/or sequential occurrence of several phenomena including recombination, pseudorecombination, and/or synergy among cassava geminiviruses (Ref. 72). It also appears that tomato-infecting begomoviruses that have emerged in the last 20 years around the Nile and Mediterranean Basins probably resulted from numerous recombination events (Ref. 74). In addition, a natural recombinant between tomato yellow leaf curl Sardinia virus and tomato yellow leaf curl virus was detected in southern Spain with a novel pathogenic phenotype that might provide it with selective advantage over the parental genotypes (Ref. 75). Finally, analysis of

a newly described *Curtovirus* species associated with disease of spinach in southwest Texas suggests that it may be the result of recombination among previously described *Curtovirus* species (Ref. 76).

In addition to virus-virus recombination, recombination has also been found to occur between virus and plant host RNA. Sequence analysis of the 5' terminal sequence of potato leafroll virus (PLRV) suggests that it arose via recombination with host mRNA (Ref. 77). Evidence suggests that such recombination events can affect virus virulence (for review see Ref. 78). Like a plant host genome, transcripts of viral transgenes would be available for recombination with infecting viruses, and portions of the transgene could thus be incorporated into the replicating virus. Several laboratory experiments have investigated the potential for recombination between viral transgenes and infecting viruses of the same species. These experiments show that recombination can occur between viral transgenes and both RNA viruses (Refs. 79, 80, 81, 82, and 83) and DNA viruses (Refs. 84, 85, 86, and 87). However, the relevance to PVCP-PIPs of the latter experiments with DNA viruses is unclear because the transgenic plants used in the experiments actually show no viral resistance; attempts to develop transgenic DNA virus-resistant plants in general have had little success (Ref. 57). In addition, to facilitate the detection of recombinants, most of these experiments were conducted under conditions of high selective pressure favoring the recombinant, i.e., only recombinant viruses were viable. The selective pressure under normal field conditions would likely favor the parental viruses rather than a recombinant as parental viruses will be competent in all of the functions needed for propagation and will outnumber the new recombinant.

ii. *Heterologous encapsidation*. Heterologous encapsidation occurs when the coat protein subunits of one virus surround and encapsidate the viral genome of a different virus. The coat protein, possibly in conjunction with other viral factors, is often essential for transmission and responsible for conferring the high degree of vector specificity. Therefore, a heterologously encapsidated viral genome may be transmitted by the vectors of the virus contributing the coat protein rather than the vectors of the virus contributing the viral genome. For many viruses, transmission from plant to plant occurs by insect vectors, and each virus tends to be transmitted by only one type of insect (Ref. 1). To the extent that vectors visit different groups of plants, vectors carrying a heterologously encapsidated viral genome may carry it to a plant the virus does not normally encounter (Ref. 59).

Most evidence of heterologous encapsidation is derived from laboratory or greenhouse studies. Even though there is a high frequency of mixed infections in nature, most mixed infections do not lead to heterologous encapsidation, and those virus interactions that do occur tend to be very specific rather than random interactions between unrelated viruses (Ref. 88). Only among some types of plant viruses is heterologous encapsidation regularly observed. Its frequency depends on the relationship between the viruses involved, being more likely to occur among closely related viruses (Ref. 89). An expansion of aphid vector specificity due to heterologous encapsidation was first observed in plants infected with two different isolates of barley yellow dwarf virus (BYDV; Ref. 90) and was later shown to be a general phenomenon among these viruses in natural populations of several plant species (Ref. 91). Heterologous encapsidation was also shown to occur in potyviruses. An isolate of zucchini yellow mosaic virus (ZYMV) that is normally non-aphid transmissible due to a transmission-deficient coat protein was found to be transmitted by the aphid vector due to heterologous encapsidation when in a mixed infection with another potyvirus, papaya ringspot virus (Ref. 92). Heterologous encapsidation is essential for movement of some viruses. For example, umbraviruses do not encode a coat protein, and therefore transmission between plants occurs through encapsidation by an aphid-transmissible luteovirus coat protein (Ref. 93).

Heterologous encapsidation is considered a possible environmental concern associated with PVCP-PIPs because of the potential that if a virus is heterologously encapsidated by a PVC-protein, the viral genome might be able to spread to plants the virus ordinarily had no means of reaching and thus could not have infected. Experimental studies have shown that some PVC-proteins in transgenic plants have the ability to encapsidate even unrelated infecting viruses (Refs. 94, 95, 96, and 97). However, heterologous encapsidation involving a viral transgene can only occur if an expressed coat protein possesses the appropriate physical parameters to encapsidate the viral genome of infecting viruses. When transgenic plants containing a PVCP-PIP display resistance with very low or no levels of PVC-protein expression (e.g., due to PTGS), the probability of heterologous encapsidation would be very small or non-existent. (For a more detailed discussion of PTGS and suppression of gene silencing, see Unit II.E. above and Unit IV.F. of the companion document also appearing in today's **Federal Register**.)

Environmental concerns associated with heterologous encapsidation when PVC-protein is expressed appear to be largely mitigated by several factors. One, the heterologously encapsidated viral genome may not be able to replicate in the new host plant and could therefore not actually infect it. In addition, if replication is possible in the new plant, the replicating viral genome encodes for and thus would produce its own coat protein rather than that which heterologously encapsidated it. This virus would not be transmitted by the new vector that brought the heterologously encapsidated genome to the new host plant. The epidemiological consequences of such heterologous encapsidation would thus be limited. Another consideration for some viruses is that effective vector transmission may depend on more than the coat protein (Refs. 98 and 99), requiring regions of the viral genome not included in PVCP-PIPs as defined for this proposal, e.g., coat protein read-through domains or helper factors. Thus, in such cases, the coat protein that could potentially heterologously encapsidate another viral genome would not contain all the parts necessary to lead to a change in vector specificity. In addition, in large monocultures of crop plants, a vector is most likely to move from plant to plant within the field and to transmit even a heterologously encapsidated viral genome to a plant that the virus is already able to infect (Ref. 98). Finally, as with recombination, as long as the PVC-protein expressed in the transgenic plant is from a virus that normally infects the plant in the area where it is planted, the outcome of any heterologous encapsidation that may occur is expected to be the same in transgenic plants as in natural, mixed infections.

In addition to these considerations, EPA evaluated whether a virus that is heterologously encapsidated and carried to a new host plant might be exposed to a vector that feeds on the new host plant and perhaps other plants the virus ordinarily could not access. EPA considered whether this new vector might in some cases be able to transmit the virus even though the virus would now be encapsidated in its own coat protein, thereby expanding the virus' vector range. A new vector could

possibly transfer the virus to new host plants, thus expanding the plant host range as well (Ref. 57). EPA considers expansion of host range through heterologous encapsidation to be an extremely unlikely outcome because such an outcome depends on each event in a series of rare events occurring. Should the probability of occurrence of any one event in this series be zero, the adverse event of an expanded host range would not occur. In addition to the events enumerated above, additional events must also occur. First, a virus must be heterologously encapsidated, an event that is possible only for some viral genome-coat protein combinations. Second, a new vector must transmit the encapsidated viral genome. Third, the transmission must be to a new host plant. Fourth, the heterologously encapsidated viral genome must be able to replicate in the new host plant. Fifth, the resulting virus, now encapsidated in its own coat protein, must be exposed to a new vector the virus never encountered before that is nevertheless able to transmit it. Finally, this vector must transmit the virus to a new plant that the virus' prior vectors never visited. For such a series of events to be novel, the viruses, vectors, and plants involved must have had no previous opportunity to interact, and it is rare for such a condition to be met. For example, it is known that many viruses are transmitted by polyphagous insects, which would have already allowed the viruses to be introduced to many potential plant species even in the absence of heterologous encapsidation (Ref. 57). Moreover, viruses may be transmitted at low frequency by a range of species other than their primary vector or mechanically, e.g., through the practices of modern agriculture (Ref. 98).

Another scenario EPA considered is one where a high enough frequency of vector transmission to a new host plant due to heterologous encapsidation might mean that secondary spread among new plant hosts might not be required for the phenomenon to affect the population, assuming that the virus is able to decrease the new host plant's growth and/or reproduction. Although this scenario may be more likely to occur than an expansion of host range given that fewer rare events would have to occur, any impact on the affected plant population would be highly localized being confined to plants in or near transgenic crop fields. Such negative impacts are unlikely to be sufficiently detrimental to require FIFRA regulation given their localized nature and the probability that common agricultural practices (e.g., vector control) could be used to manage the problem. Moreover, although isolated instances of transmission may occur, a significant proportion of a plant population is unlikely to be infected in such a scenario. For example, a field experiment (discussed in Unit III.D.1.iv.) showed that heterologous encapsidation led to infection of only 2% of plants compared to 99% of plants infected under similar conditions by a virus that is not heterologously encapsidated (Ref. 100). Most importantly, the heterologously encapsidated virus will still have no way to spread among or beyond the plants of the affected population. In the case where a plant population contains relatively few individuals such that the impact of single plant infections would be magnified, plant infections are even less likely to occur because in addition to the inefficient nature of heterologous encapsidation, the vector would be more likely to feed on the more abundant transgenic crop plants. In some cases a vector may have a strong preference for a specific plant over even closely related plants (Ref. 101).

Finally, EPA evaluated whether after expansion to a new host, rapid selection of variants best adapted to the new environment might lead to the evolution of a new virus (Ref. 57). However, in addition to requiring several of the rare events discussed above to occur, this phenomenon is unlikely to be entirely novel in any circumstance. All viruses that are occasionally heterologously encapsidated and transmitted to a new plant host have had the opportunity to adapt to new plant environments. The opportunities for rapid viral evolution presented by transgenic plants containing PVCP-PIPs would not be fundamentally different from what occurs in nature under reasonably likely circumstances. Rapid viral evolution after heterologous encapsidation is not dependent on the unique combination of viruses that interact but rather the introduction of a virus to a new plant host, an event that likely occurs in nature at some frequency for most viruses either through heterologous encapsidation or through occasional transmission that occurs mechanically or from secondary vectors (Ref. 98).

iii. *Synergy*. In synergy, another type of viral interaction, the disease severity of two viruses infecting together is greater than expected based on the additive severity of each virus alone. For example, when a plant containing potato virus X (PVX) is coinfected with any of a number of potyviruses including tobacco vein mottling virus, tobacco etch virus, and pepper mottle virus, the disease symptoms are considerably worsened and PVX accumulates to a greater concentration (Ref. 102). A listing of reported viral synergisms has been compiled (Ref. 103).

In developing this proposal, EPA addressed whether synergy could occur between an infecting virus and a PVCP-PIP, thereby increasing the severity of the infecting virus and whether any consequences for the environment could result from such an increase. For disease severity to worsen, the PVC-protein must be at least one of the factors causing synergy. However, the coat protein is considered much less likely to be responsible for synergism than other parts of the virus (Refs. 104 and 105), and a PVCP-PIP producing other viral proteins would not qualify for this proposed exemption. In addition, any negative effects are expected to manifest primarily in the transgenic crop itself. Furthermore, any negative effects are expected to be self-limiting because any plants containing a PVCP-PIP that is prone to display synergy with viruses common in the areas of planting would be quickly abandoned once such effects were detected, perhaps as early as the field-testing stage of product development. Synergistic interactions can be evaluated in transgenic plants before deployment by experimental inoculation with all of the viruses likely to be encountered in the field (Ref. 98). Developers have a strong incentive to undertake such efforts to ensure the efficacy of their product after deployment.

iv. *Field experiments*. The experiments referenced in Units III.E.2.i. through iii. above investigated potential viral interactions in transgenic plants containing a PVCP-PIP under laboratory conditions. However, equally important is consideration of the likelihood and potential impact of viral interactions under natural field conditions (Ref. 106). Relatively few field studies have been conducted to address the questions EPA is evaluating for this proposal, but the Agency has carefully considered the available literature in developing this proposed exemption.

A 6–year experiment searched for and failed to find evidence of interactions involving viral transgenes in 25,000 transgenic potato plants transformed with various PLRV coat protein constructs. Plants were exposed to infection by PLRV by direct inoculation, plant-to-plant spread, or natural exposure. In field experiments, plants were also naturally exposed to the complex of viruses that occur in the region. Both the greenhouse and field tests failed to show any change in the

type or severity of disease symptoms, and all viruses isolated were previously known to infect the plants and had the expected transmission characteristics (Ref. 107). These results suggest that viral interactions leading to evolution of new viruses and/or more severe viral disease are events too rare to be detected in a field trial of this size and duration.

A 2–year experiment with transgenic melon and squash expressing coat protein genes of an aphid-transmissible strain of CMV failed to yield evidence that either recombination or heterologous encapsidation enabled spread of an aphid non-transmissible strain of CMV in the field (Ref. 108). A similar experiment used transgenic squash expressing coat protein genes of an aphid-transmissible strain of watermelon mosaic virus (WMV). Plants were mechanically inoculated with an aphid non-transmissible strain of ZYMV, and subsequent transmissions of the virus (assumed to be vectored by aphids) were assessed. Infections of ZYMV were not detected in nontransgenic fields, but the virus infected up to 2% of plants in transgenic fields. Several lines of evidence suggested ZYMV infection was mediated by the WMV PVC-protein heterologously encapsidating the ZYMV viral genome. However, the virus spread over short distances, and transmission at a low rate failed to lead to an epidemic of ZYMV in fields of WMV-resistant transgenic squash despite the presence of optimal conditions for transmission (Ref. 100). These results support the contention that even if heterologous encapsidation involving a PVC-protein were to occur, the impact is likely to be negligible because each plant infection by a heterologously encapsidated virus requires a series of rare events to occur. Viral infection by normal routes of transmission can be at least an order of magnitude more efficient and lead to relatively greater impacts (Ref. 100).

An experiment to assess the biological and genetic diversity of California CMV isolates sampled before and after deployment of transgenic melon containing the CMV coat protein gene documented only one CMV isolate that had significant sequence changes. However, the same change was seen with infection of non-transgenic plants, suggesting that this isolate did not result from recombination between the transgene and an infecting virus (Ref. 109). The only field experiment to directly assess the effect of recombination in a transgenic plant containing a PVCP-PIP found no detectable grapevine fanleaf virus (GFLV) recombinants containing the inserted coat protein sequence over the course of a 4–year study (Ref. 110). Test plants consisted of nontransgenic scions grafted onto transgenic and nontransgenic rootstocks that were exposed over 3 years to GFLV infection at two locations. Analysis of challenging GFLV isolates revealed no difference in the molecular variability among isolates from 190 transgenic and 157 nontransgenic plants, or from plants within (253 individuals) or outside (94 individuals) of the two test sites.

2. *Proposed exemption criterion*. The information in Units III.E.2.ii. through iv. suggests that heterologous encapsidation very rarely leads to changes in virus epidemiology that could have any large-scale impact and that synergy in plants containing PVCP-PIPs is also unlikely to cause any widespread environmental harm. Consistent with these observations, the 2004 SAP noted that ''except perhaps for a very few cases, neither heterologous encapsidation nor synergy should be considered to be of serious concern'' (Ref. 60). However, the Agency believes that in all cases, concerns associated with these types of viral interactions are likely to be limited in scope (for reasons discussed in Units III.E.2.ii. through iii.) such that the determination can be made that they pose low risk to human health and the environment. EPA therefore concludes that PVCP-PIPs present low risk with respect to heterologous encapsidation and synergy and that PVCP-PIPs could be exempted without further qualification or requirements to address these endpoints.

However, EPA is not able to conclude at this time that all PVCP-PIPs are low risk with respect to recombination (although see Unit VII for a discussion of EPA's request for information that might allow the Agency to reach such a conclusion). The Agency notes that the vast majority of interactions between a viral transgene and an infecting virus are expected to be no different from those that would occur in a natural mixed infection of the respective viruses and would not cause any adverse environmental effects beyond what could occur in the absence of the PVCP-PIP. Nevertheless, the information discussed in Unit III.D.1.i. suggests that recombination among viruses may lead to rare instances of adverse changes in virus epidemiology and/or pathogenicity, e.g., a host range expansion. Based on the available information, EPA is not able to rule out that viable, recombinant viruses containing a portion of a PVCP-PIP could arise in transgenic plants and that in a small set of circumstances (discussed in Unit III.D.2.i.) such recombinants could be unlike those that could arise naturally. EPA agrees with the conclusions of the 2004 SAP that ''[i]n contrast to heterologous encapsidation and synergy, at least in theory, the impact of recombination could be much greater, since there is now abundant bioinformatic evidence that recombination has indeed, as long suspected, played a key role in the emergence of new viruses over evolutionary time'' (Ref. 25). The 2005 SAP concurred with this conclusion by noting that there ''are a few scenarios, however, in which recombination may have an incrementally higher probability of creating a virus with new properties. In conclusion, the Panel recommended the need for the Agency to have criteria to assess the level of risk'' (Ref. 11).

The Agency notes that the 2005 SAP concluded that ''the likelihood for 'novel' interactions is very low, and the environmental concerns that might result from using PVCP-PIPs in the United States... is lower than that which occurs naturally from mixed virus infections'' (Ref. 11). In addition, ''it was repeatedly stated that the consequences of any recombination event are minimal. This conclusion was based on the fact that nearly every plant on the planet is harboring multiple virus infections with both closely related and taxonomically distinct viruses, with essentially no new viruses emerging with substantially different properties and causing wide pandemics or undesirable environmental effects'' (Ref. 11). In spite of such comments, EPA's proposal contains § 174.27(b) because of the overall context of the Panel's response which articulated several factors (discussed in Unit III.D.2.) that should be considered when evaluating recombination. EPA believes § 174.27(b) is consistent with these comments of the 2005 SAP because the Agency believes these comments apply only when considering the whole set of PVCP-PIPs that are likely to be developed. For the PVCP-PIPs that would only qualify for an exemption without the limitations provided by § 174.27(b), EPA does not believe the Agency can conclude low risk with respect to recombination because the 2004 and 2005 SAPs have identified specific instances where this general conclusion may not hold.

The few field evaluations conducted (discussed in Unit III.D.1.iv.) suggest that adverse environmental effects due to recombination in transgenic plants containing PVCP-PIPs are unlikely to occur at least on a small scale over a short time period. However, large acreages of plants containing a PVCP-

PIP grown over many years may provide increased opportunity for rare events to occur that are unlikely to be detected in experimental studies (Ref. 104). In addition, none of the experimental systems described above would be predicted to involve viruses that would otherwise not be expected to interact in a mixed infection found in nature. Given the limited amount of field data available, particularly data relevant to the circumstances EPA has identified as being of highest concern (i.e., those that could lead to novel interactions), EPA is limiting the proposed exemption to those PVCP-PIPs for which novel viral interactions are unlikely to occur. When EPA consulted the 2004 SAP about situations in which novel viral interactions might be a concern, the Panel agreed ''that recombination is a concern when the two contributing viruses have not previously had a chance to recombine'' (Ref. 25).

In addition to considering the potential for novel viral interactions to occur, EPA also considered whether transgenic plants containing PVCP-PIPs might have a changed *frequency* of viral interactions. The frequency could *decrease* because the cellular concentration of viral RNA transcripts expressed from transgenes may be orders of magnitude lower than the concentration of viral RNA commonly found in natural, mixed infections (Ref. 111), reducing the opportunity for recombination. The concentration of infecting viral RNA from the target virus would also be reduced considerably if the PVCP-PIP is efficacious, particularly when the mechanism of resistance relies on PTGS to remove viral RNA transcripts with homology to the transgene (Ref. 112), thereby also reducing the opportunity for recombination. However, the frequency of interactions could also *increase* given that transgene RNA expressed from a constitutive promoter could be available for interactions with infecting viruses in all cells of the plant at all times - unlike RNA from a virus in a natural infection. When a virus invades a cell, it often replicates and then moves to other cells within the plant. The RNA remaining in the initially infected cell becomes encapsidated and may no longer be available for interactions with another invading virus (Ref. 113). When EPA presented this issue to the 2004 SAP, the panel responded that ''no increase in heterologous encapsidation should be anticipated in PVCP-PIP plants'' and ''the Panel believed that in general recombination was more likely to occur in transgenic plants than in non-bioengineered plants.'' Nevertheless, the Panel agreed ''that the important questions are not the relative likelihood for recombination to occur, but rather whether recombinants in transgenic plants are different from those in non-transgenic plants and whether they are viable'' (Ref. 25). Thus, EPA's proposal focuses on situations in which novel recombination events could occur due to the presence of a PVCP-PIP.

i. *Proposed categorical exemption criterion in § 174.27(b)(1).* In developing the proposed categorical exemption for a subset of PVCP-PIPs in which a developer could self-determine whether the criteria were met, EPA sought to clearly identify those situations that pose low risk with respect to viral interactions.

A PVCP-PIP would meet the viral interactions criterion under § 174.27(b)(1) if:

(i) The viral pathotype used to create the PVCP-PIP has naturally infected plants in the United States and naturally infects plants of the same species as those containing the PVCP-PIP, or

(ii) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant.

Recombination between the coat protein gene of the PVCP-PIP and infecting viruses would be expected to be of little concern in certain instances: when such recombination would involve segments of viruses that are judged likely to have had the opportunity to recombine in a natural, mixed infection (and therefore any recombinants produced are unlikely to be novel), and when PTGS results in only small, cleaved pieces of RNA being available for recombination. The former situation would be met if the conditions of the criterion in proposed § 174.27(b)(1)(i) are met. The latter situation would be met if the conditions of the criterion in proposed § 174.27(b)(1)(ii) are met. EPA is proposing that no further data or information would be needed to evaluate risks associated with recombination when § 174.27(b)(1) is satisfied under either § 174.27(b)(1)(i) or § 174.27(b)(1)(ii), and therefore no Agency review would be necessary. The developer may make this determination.

If the viral pathotype used to construct the PVCP-PIP was isolated in the United States from the same plant species as was engineered to contain the PVCP-PIP, the PVCP-PIP would meet the proposed criterion in § 174.27(b)(1)(i). It should be noted that this proposed criterion would be used in concert with the proposed protein production criterion in § 174.27(c) discussed below in Unit III.E.2., which ensures that any modifications from the natural isolate encode a protein that is no more than minimally modified from a natural virus coat protein. Thus, any coat protein that satisfies § 174.27(c) would be extremely unlikely to confer significantly different properties on any virus that could potentially acquire the coat protein through recombination with the genetic material of the PVCP-PIP.

The Agency asked the FIFRA SAP during the October 2004 meeting to what extent PVCP-PIPs in plants might present a potential concern should interactions with infecting viruses occur. The Panel expressed concern only ''about certain limited situations'' and clarified that ''in most cases there is little *a priori* reason to believe that recombinants between viruses and transgenes will be more of a problem than recombinants between two viruses infecting the same plant, unless transgenes are derived from severe or exotic isolates. The general recommendation to use mild, endemic isolates as the source of the transgene (e.g. Hammond et al. 1999) should minimize any potential for creation of novel isolates that would not equally easily arise in natural mixed infections'' (Refs. 25 and 57). The Agency's proposed § 174.27(b)(1)(i) is consistent with this 2004 SAP recommendation because it excludes exotic virus isolates as the source of the PVCP-PIP transgene. Although proposed § 174.27(b)(1)(i) does not require that the virus isolate be a ''mild'' form of the virus, it does ensure that when virus isolates capable of causing severe cases of viral disease are used, the PVCP-PIP may only meet § 174.27(b)(1)(i) if the viral pathotype was present in the natural system and therefore should pose no risk of novel interactions.

The 2005 SAP offered a decision flowchart indicating a point at which the Agency should identify the few scenarios where recombination may be of concern: ''the question arises as to whether recombination of the sequence could lead to a significant change in the properties of the recombinant over the original properties of the superinfecting virus. Significant changes include increase in pathogenicity, increase of host range or change of vector'' (Ref. 11). EPA believes that consideration of whether the conditions of proposed § 174.27(b)(1)(i) are met addresses whether the potential exists for significant changes in the properties of a recombinant virus compared to what

might occur in a natural, mixed infection.

In addition to excluding exotic virus isolates, proposed § 174.27(b)(1)(i) also excludes PVCP-PIPs that are inserted into a plant species that is not naturally infected by the virus used to create the PVCP-PIP. Most PVCP-PIPs are created from viruses that do naturally infect the plant species into which they are inserted because greater efficacy is achieved when a virus most similar to the target virus is used as the source of the sequence used in the PVCP-PIP. However, virus-resistant transgenic plants have been created where this is not the case (Ref. 114). In these situations, a virus is introduced into a system where it does not naturally occur, and viruses with which it does not otherwise interact may be present in that system. The Agency cannot *a priori* determine that such interactions are safe because there is no experience upon which to base such a finding.

Proposed § 174.27(b)(1)(i) is also consistent with the 2005 SAP's recommendation to consider ''whether recombination of the sequence could lead to a significant change in the properties of the recombinant over the original properties of the superinfecting virus'' (Ref. 11). When the viral pathotype used to create the PVCP-PIP has naturally infected plants in the United States and naturally infects plants of the same species as those containing the PVCP-PIP, the sequences that could interact would be expected to already have opportunities to interact in nature and thus no novel recombinants should be produced.

The Agency's proposed § 174.27(b)(1)(ii) is consistent with the 2005 SAP's recommendation to consider whether the PVCP-PIP expresses PVC-protein when evaluating the potential consequences of recombination (Ref. 11). When a PVCP-PIP expresses no PVC-protein because it is designed to mediate resistance through PTGS, recombination would be of little concern because ''recombination between a full-length viral RNA and a cleaved small RNA resulting from PTGS would yield a truncated non-functional RNA. Therefore, a PTGS transgene poses negligible potential to yield novel recombinant viruses'' (Ref. 11). EPA therefore makes part of its proposal two circumstances when, according to the 2005 SAP, the PVCP-PIP can only mediate resistance through PTGS because it would produce no PVC-protein: when the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant (Ref. 11). See Unit III.D.2.ii. below for a discussion of how other constructs mediating resistance through PTGS could meet § 174.27(b).

One Panel member noted, ''PTGS results in small RNA from the PIP and the infecting virus that could, in certain circumstances, be recombinatorial.'' However, the Panel concluded ''this minimal RNA would not confer a phenotype to the recombinant, would result in just a few nucleotide changes in a potential recombinant, and thus would be irrelevant'' (Ref. 11).

EPA proposes to define the term ''naturally infect'' to mean ''to infect by transmission to a plant through direct plant-to-plant contact (e.g., pollen or seed), an inanimate object (e.g., farm machinery), or vector (e.g., arthropod, nematode, or fungus). It does not include infection by transmission that occurs only through intentional human intervention, e.g., manual infection in a laboratory or greenhouse setting.'' The Agency is proposing this definition specifically to exclude transmission that occurs only through intentional human intervention because such transmission would have little relevance to normal virus infection. EPA recognizes that humans may play an inadvertent role in infection (e.g., by transmitting the virus on farm machinery). Such unintentional (and often unavoidable) transmission can be an important means of virus transmission, leading to the natural presence of viruses in plants. EPA therefore proposes to include this mode of incidental transmission in the definition of naturally infect.

EPA uses the term ''viral pathotype'' rather than the more generic term ''virus'' in response to the October 2004 FIFRA SAP comment that ''[n]ot all isolates of a virus infect and cause disease in all plant genotypes and, as a consequence, the unqualified use of the term 'virus' when setting a condition for applicants to the Agency [is] not adequate in this context. It is therefore appropriate in the context of biosafety as well as virus epidemiology to recognize the value of defining specific viral pathotypes or host range variants.'' The 2005 SAP was asked to comment on the use of this term and responded, ''there was not much discussion of this term. The Panel suggested that logic says that local or indigenous virus isolates, or those with significant sequence similarity, will be used to generate PVCP-PIPs. From what we know now, only those viruses with high sequence identity will be useful as sources of the PVCP-PIP transgene.'' EPA agrees that generally viral pathotypes that meet § 174.27(b)(1) will be those most effective for creating PVCP-PIPs and will therefore be the most commonly used. However, EPA considers the limitations imposed by this term to be necessary because the Agency cannot conclude that viruses not meeting this criterion would be low risk with respect to recombination.

In this proposed criterion and in § 174.27(c) discussed below, EPA uses the phrase ''genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance,'' rather than the phrase ''genetic material necessary for the production,'' to indicate that regulatory regions, such as promoters, enhancers, or terminators, need not be considered in evaluating whether a PVCP-PIP satisfies these criteria. EPA is not proposing to amend the definitions for ''genetic material necessary for the production'' or ''regulatory region,'' both found at 40 CFR 174.3, and is not seeking any comment on these definitions.

ii. *Proposed exemption criterion conditional on Agency determination in § 174.27(b)(2).* The Agency recognizes that many PVCP-PIPs may pose low risk with respect to recombination even though they fail to satisfy § 174.27(b)(1). Therefore, EPA is proposing an approach under which PVCP-PIPs that fail to meet § 174.27(b)(1) could still meet § 174.27(b), subject to an Agency review to determine whether they meet a different set of conditions related to this issue. Under this proposed approach, a PVCP-PIP would meet § 174.27(b) under § 174.27(b)(2) if the Agency determines that viruses that naturally infect the plant containing the PVCP-PIP are unlikely to acquire the coat protein sequence through recombination and produce a viable virus with significantly different properties than either parent virus.

The conditions in proposed § 174.27(b)(1) address the potential for recombinants to arise unlike those expected in natural mixed infections primarily by ensuring that no novel viral interactions occur. Under proposed § 174.27(b)(2), a PVCP-PIP could qualify for exemption even when novel viral interactions could occur providing steps were taken to ensure that an infecting virus would not acquire a portion of the PVCP-PIP coat protein sequence through recombination and produce a viable virus with significantly different properties than either parent virus.

Experimental evidence has suggested a number of ways coat protein genes of certain viruses may be modified in constructing a PVCP-PIP to reduce the possibility they would participate in a

recombination event with an infecting virus. For example, removing the 3′ untranslated region (UTR) in the coat protein mRNA transcript may be effective at reducing recombination for viruses that carry the initiation promoters of RNA replication in this region (Ref. 115). Evidence suggests that recombination among RNA viruses occurs via template switching by the viral replicase during replication such that a hybrid molecule is formed (Ref. 116). Inclusion of the 3′ UTR may enable replication to begin on the mRNA transcript and then switch to the RNA of the invading virus. Removal of this region would necessitate two separate template-switching events to form a successful recombinant and thus reduce its likelihood of occurrence (Ref. 80). Experiments with CCMV demonstrated that deletions in the 3′ UTR did indeed reduce the recovery of recombinant viruses (Ref. 117). Since functional resistance is still conferred by constructs containing a CP lacking the 3′ UTR, this region may not be necessary. Other techniques that have been suggested include:

- Reducing the extent of shared sequence similarity between the infecting virus and the transgene to reduce the opportunities for homologous recombination (Ref. 118).
- Excluding any sequences containing replicase recognition sites that are potential sites of recombination and any sequences known or thought to be recombination hotspots, e.g., promoters for genomic and subgenomic RNA synthesis (Ref. 119).
- Avoiding potential hairpin structures in the transgene that might function as acceptor structures for the replicase complex (Ref. 120).

It is important to note that any PVC-protein produced must be evaluated under § 174.27(c) in order for the PVCP-PIP to qualify for exemption. Some techniques that may enable a PVCP-PIP to meet § 174.27(b)(2) would preclude the PVCP-PIP from meeting § 174.27(c)(1) and necessitate a review under § 174.27(c)(2). For example, a construct could meet proposed § 174.27(b)(2) if it contained portions of several different coat protein genes in tandem, linked together in such a way that if the sequence were translated it would yield a non-functional coat protein of no use to a virus. A virus that acquired this entire sequence through recombination in exchange for portions of its own genome would likely be nonviable. As another example, a construct might meet proposed § 174.27(b)(2) if it contained a very small portion of a coat protein gene. In such cases, a virus would be unlikely to acquire this sequence through recombination without picking up additional pieces of genetic material from the construct or the plant genome that would likely render the virus nonviable. Or, if a virus did acquire a piece of just the small part of the coat protein sequence contained in the transgenic plant, it would likely not be large enough to significantly change the properties of the parent virus. Any PVC-protein produced from either such construct would fail to meet § 174.27(c)(1) but could be evaluated under and may nevertheless meet § 174.27(c)(2) (see Unit III.E.2. below).

EPA recognizes the comments of the 2004 SAP that ''methods for minimizing recombination are only partially effective. For this reason, the question remains whether novel recombinants would be created in transgenic plants, and simply reducing the frequency of these events is not an answer to the question'' (Ref. 60). However, EPA believes that a combination of two or more methods, or even perhaps a single method in some cases, could be employed to reduce the expected frequency of recombination such that the Agency would be able to make a determination that a PVCP-PIP would pose low risk with respect to viral interactions. EPA asked the 2004 SAP ''which methods are sufficiently effective such that requiring measurement of recombination rates would be unnecessary. The Panel doubted if the... methods [discussed] are sufficiently effective to warrant the reduction of recombination rates below the level that the actual measurement will be unnecessary'' (Ref. 25). However, the Agency would have the opportunity during the case-by-case Agency review under § 174.27(b)(2) to consider the particular viral system and whether literature supports the contention that the recombination reduction techniques are likely to be sufficiently effective in the system in which they are employed. EPA anticipates that the Agency could base this determination on the expected reduction in frequency of recombination as determined from the literature and that actual measurement of recombination rates may be unnecessary. Given that there is no universally applicable method for reducing recombination frequency and this type of case-by-case consideration of the particular virus system in question must be conducted, EPA believes an Agency review is needed to make this determination. With an Agency determination under § 174.27(b)(2), EPA would create a criterion that would encompass a larger set of those PVCP-PIPs that pose low risk with respect to viral interactions than are covered under § 174.27(b)(1).

Section 174.27(b)(2) is consistent with the advice of the 2005 SAP in that it incorporates the portions of the proposed decision tree that allow consideration of whether there are ''features controlling recombination,'' whether ''the protein [is] complete,'' and whether the plant host contains ''genes that reduce recombination'' (Ref. 11). Likewise, the review procedures for determining whether a PVCP-PIP met the conditions of § 174.27(b)(2) would also be able to consider ''the type of RNA-dependent RNA polymerase (RdRps) encoded by the superinfecting virus and the compartmentalization of its site of replication'' as suggested by the 2005 SAP (Ref. 11). Although EPA notes that there was some disagreement among the Panel members about the appropriateness of including such information as part of the flow chart, the Agency believes that this information could be reasonably considered when available and when sufficient knowledge about the plant/virus system exists such that it would offer useful information for evaluating this criterion. Overall, § 174.27(b) thus enables the Agency to consider either under § 174.27(b)(1) or § 174.27(b)(2) all of the factors mentioned in the flowchart by the 2005 SAP.

3. *Historical approaches still under consideration*. EPA's proposed exemption in 1994 did not contain any criteria related to viral interactions. However, since that time, many additional scientific papers and reviews have been published on this topic. Most affirm the general safety of PVCP-PIPs with respect to viral interactions, but some call into question assumptions of how generically this conclusion holds across all PVCP-PIPs. For example, although the 2000 NRC report stated that ''[m]ost virus-derived resistance genes are unlikely to present unusual or unmanageable problems that differ from those associated with traditional breeding for virus resistance,'' the NRC's report also suggested that their conclusions were based on the assumption that certain risk management strategies should or would be implemented, e.g., elimination of specific sequences to limit the potential for recombination (Ref. 10). EPA believes the Agency's 1994 conclusion of low probability of risk still holds for most PVCP-PIPs. However, in order to grant an exemption under FIFRA, EPA must be able to make such a finding for all PVCP-PIPs covered by the exemption and must make its safety determination

in the absence of any regulatory oversight under FIFRA that could ensure mitigation measures, such as those discussed in the NRC report, were employed. Therefore, it appears prudent at this time to limit this proposed exemption with a criterion that restricts the potential for novel recombination events, as these have been identified as the rare situation in which viral interactions in plants containing a PVCP-PIP may lead to adverse environmental effects.

EPA presented a set of conditions to the 2004 SAP and asked whether they would significantly reduce either the novelty or frequency of viral interactions in plants containing PVCP-PIPs such that the Agency would not need to regulate the PVCP-PIP (Ref. 25). The first proposed condition was that ''the genetic material of the PVCP-PIP is translated and/or transcribed in the same cells, tissues, and developmental stages naturally infected by every virus from which any segment of a coat protein gene used in the PVCP-PIP was derived.'' EPA considered such a condition because with a PVCP-PIP, plants may express viral genes in cells and/or tissues that the virus does not normally infect. Genetic promoters currently used in most transgenic plants cause constitutive expression of transgenes at developmental stages that might otherwise be unaffected by viral infection and often in tissues that the virus does not normally infect (Ref. 113). For example, luteoviruses are normally expressed only in phloem tissue, but the cauliflower mosaic virus (CaMV) promoter, commonly found in existing PIP constructs, would drive expression of luteoviral coat protein in all plant cells. Some evidence suggests that in natural infections different viruses have different temporal or spatial expression patterns that would limit their interactions (Refs. 63, 121, and 122). However, the 2004 SAP concluded that such a condition would be of limited utility because ''[m]ost plant viruses are present in a wide range of cell and tissue types'' (Ref. 25).

The second condition proposed to the 2004 SAP was that ''the genetic material of the PVCP-PIP contains coat protein genes or segments of coat protein genes from viruses established throughout the regions where the crop is planted in the United States and that naturally infect the crop into which the genes have been inserted.'' EPA considered the first part of this criterion because plants may be engineered with coat protein genes from an exotic strain of a virus that may be more virulent or have other properties different from endemic isolates. Interactions between a PVCP-PIP based on such virus sequences and infecting viruses could potentially change the epidemiology or pathogenicity of the infecting viruses. The 2004 SAP concurred that ''using such an exotic coat protein gene would open possibilities for novel interactions.'' EPA's current proposed § 174.27(b) thus excludes from exemption PVCP-PIPs based on coat protein genes from exotic viruses unless steps have been taken to reduce the frequency of recombination.

EPA considered the second part of this 2004 criterion (i.e., the genetic material of the PVCP-PIP contains coat protein genes or segments of coat protein genes from viruses... that naturally infect the crop into which the genes have been inserted) because in heterologous resistance a plant may be resistant to infection by a particular virus in spite of having the coat protein gene of another virus incorporated into its genome. For example, coat protein genes from LMV were used to provide resistance to PVY in tobacco which is not infected by LMV (Ref. 114). In such plants, LMV sequences might have a new opportunity to interact with viruses that infect tobacco. The 2004 Panel concluded that ''[w]hat is described here is most often implemented: in designing a PVCP transgene, better efficacy is often observed if it is as similar as possible to the target virus.'' Nevertheless, EPA believes that EPA's current proposed criterion (b) is appropriate given that PVCP-PIPs may be developed using heterologous resistance. This criterion excludes from exemption PVCP-PIPs used in plants that the virus used to create the PVCP-PIP does not naturally infect unless steps have been taken to reduce the frequency of recombination.

The third condition proposed to the 2004 SAP was that ''the PVCP-PIP has been modified by a method scientifically documented to minimize recombination (e.g., deletion of the 3′ untranslated region of the coat protein gene). As discussed above, the 2004 SAP expressed reservation about such a criterion, and EPA recognizes that any single method for minimizing recombination may be only partially effective (Ref. 60). However, EPA believes that a combination of two or more methods, or even perhaps a single method in some cases, could be employed such that the expected frequency of recombination would be reduced to a level that would support determination that a PVCP-PIP would pose low risk with respect to viral interactions, but that such a determination could only be made on a case-by-case basis. EPA thus intends that the proposed criterion in § 174.27(b)(2)(ii) would allow the Agency to make this determination after review.

The fourth condition proposed to the 2004 SAP was that ''the PVCP-PIP has been modified by a method scientifically documented to minimize heterologous encapsidation or vector transmission, or there is minimal potential for heterologous encapsidation because no protein from the introduced PVCP-PIP is produced in the transgenic plant or the virus does not participate in heterologous encapsidation in nature.'' The 2004 SAP concluded that ''[t]his method can... be considered seriously if deemed necessary'' (Ref. 25). However, the Agency concluded (as discussed above in Unit III.D.1.ii.) that such methods are not necessary because heterologous encapsidation is so rarely likely to be of any significant ecological concern.

Based on these considerations, EPA presented a set of modified conditions to the 2005 SAP that reflected the advice of the 2004 SAP. Those conditions were the same as those that EPA is proposing today in § 174.27(b) except that § 174.27(b)(2) as submitted to the 2005 SAP included an additional provision: this criterion could be met by meeting the current conditions *or* by meeting the condition that ''the properties of the viral pathotype that are determined by the coat protein gene used to create the PVCP-PIP are substantially similar to the properties of a viral pathotype that naturally infects plants in the United States, and the viral pathotype used to create the PVCP-PIP naturally infects plants of the same species as that containing the PVCP-PIP.'' EPA is no longer proposing this condition as a means of meeting § 174.27(b) because the 2005 SAP concluded that it was ''unusable and cannot be re-written into a satisfactory form'' because of the difficulty of defining ''properties'' and ''substantially similar'' in this context (Ref. 11).

E. Production of Proteins

1. *Scientific issues*. In addition to weediness and viral interactions, a third concern associated with PVCP-PIPs relates to the potential production of proteins (called PVC-proteins) from the plant virus coat protein sequences of the PVCP-PIP, i.e., the potential for human or nontarget organism exposure to proteins that have not previously existed in nature and thus should be examined to determine whether they have potentially toxic or allergenic properties. EPA must consider the safety of any potentially expressed proteins that are part of the PIP when proposing

criteria to evaluate PVCP-PIPs for possible exemption.

EPA considered human dietary, human occupational, and nontarget exposure risks in evaluating the safety of PVC-proteins for purposes of this proposal as the Agency must do when evaluating whether a pesticide can be exempt from the requirements of FIFRA. See EPA's assessment of human dietary exposure risks and other non-occupational exposure risks published in the companion document in today's **Federal Register** that proposes to establish a tolerance exemption under FFDCA section 408 for residues of the PVC-protein portion of a PVCP-PIP.

Many, if not all, of the considerations used to evaluate the potential for novel occupational or nontarget exposures can be directly extrapolated from the discussion in this companion document describing EPA's base of experience with viruses infecting food plants. That analysis led the Agency to draw three conclusions on which it is relying to support the proposed tolerance exemption for residues of PVC-proteins in food and which can also be used to support this proposed criterion for exemption from FIFRA requirements. First, virus-infected plants have always been a part of the human and domestic animal food supply. Most crops are frequently infected with plant viruses, and food from these crops has been and is being consumed without adverse human or animal health effects. Second, plant viruses are not infectious to humans, including children and infants, or to other mammals. Third, plant virus coat proteins, while widespread in food, have not been associated with toxic or allergenic effects to animals or humans. EPA derived these conclusions from a sufficient experience and information base to support the proposed tolerance exemption and this proposed criterion for exemption from FIFRA requirements.

EPA consulted the 2004 SAP about possible nontarget effects of PVC-proteins and the validity of the Agency's risk assessment being based on the known history of safe exposure to coat proteins of naturally occurring plant viruses. Virus infected plants have always been a part of the natural environment, and organisms that interact with plants have likely been exposed to plant virus coat proteins over long periods of time. The panel confirmed that PVC-proteins within the range of natural variation of the virus would not be anticipated to present risks to nontarget organisms, concluding that, ''[l]ethal effects in animal life after feeding on PVCP-PIP plants are highly unlikely because plant viruses are not known to have deleterious effects on animal life. Additionally, animals routinely feed on non-engineered virus-infected plants and do not die.... [S]ublethal effects are not expected to be manifested in animal life, again because wildlife and insects regularly feed on non-engineered virus-infected plants with no apparent sublethal damage'' (Ref. 60).

The 2005 SAP echoed these general conclusions by pointing out that virus coat proteins ''are naturally present in the environment and no adverse effects to humans or non-targets have been reported'' (Ref. 11). However, the 2005 SAP also suggested that additional concerns might warrant evaluation, including ''indirect ecological effects (such as altered food sources, vegetative cover, or microbial communities)'' (Ref. 11). The particular concerns associated with such effects were not articulated. PVC-proteins that meet the conditions of this exemption are not expected to alter nontarget food sources because they would be so similar to plant virus coat proteins that occur naturally. Indirect effects such as changes in vegetative cover might occur if crop plants containing a PVCP-PIP are larger and/or more productive in the absence of virus infection relative to plants that are infected. However, the overall effect on nontarget organisms is still likely to be minor given that crops are often grown in the absence of viral disease even without the use of a PVCP-PIP, and PVCP-PIPs exempted by this proposal would have very limited ability to spread from crop plants to wild or weedy relatives. PVCP-PIPs are not expected to impact microbial communities because natural plant virus coat proteins are not known to have any toxic mode of action. Moreover, plant virus coat proteins already occur naturally in the environment so microbial communities are already exposed to such proteins. Some Panel members also ''expressed concern over potential effects on pollinators,'' but EPA is unaware of any scientific evidence supporting this concern. EPA concurs with other Panel members who believed that ''a history of exposure by pollinators to naturally infected plants can be taken as indicating that there are no novel risks'' (Ref. 11).

Other concerns raised by the 2005 SAP regarding nontarget and human non-dietary exposure are addressed in the companion document published in today's **Federal Register**, where they are discussed in the context of consideration of the human dietary risks associated with PVC-proteins. The companion document describes in Unit IV.C., for example, the basis for EPA's conclusion that the hazard associated with PVC-proteins that meet § 174.27(c) of this proposed exemption is sufficiently low that they do not rise to the level warranting regulation. These same arguments can be applied to PVC-proteins that meet § 174.27(c) in this proposal, even in the rare cases when nontarget exposure to a PVC-protein might be greater than the exposure to the corresponding natural plant virus coat protein. The companion document also describes in Unit IV.C. rationales that can be used to support EPA's conclusion that nontarget exposure to PVC-proteins in plant tissues that do not normally contain the corresponding plant virus coat protein is unlikely to contribute significantly to risk. Nontarget organisms would be exposed to natural plant virus coat proteins through a variety of routes and there is no evidence that they would be toxic to any nontarget organisms regardless of the route of exposure.

2. *Proposed exemption criterion.* As with the other proposed criteria discussed in this document, EPA is proposing that § 174.27(c) would have two parts: Section 174.27(c)(1) under which a developer may self-determine if a PVCP-PIP meets the conditions, and § 174.27(c)(2) under which the Agency must make the determination.

i. *Proposed categorical exemption criterion in § 174.27(c)(1).* In developing the proposed categorical exemption for a subset of PVCP-PIPs in which a developer could self-determine whether the criteria were met, EPA sought to identify clearly those situations that pose low risk with respect to protein production because any PVC-proteins produced would be within the range of natural variation. EPA wants to ensure that a long history of safe human and nontarget exposure has occurred for any PVC-protein produced from a PVCP-PIP that could qualify for this exemption. A PVCP-PIP would meet § 174.27(c)(1) if a product developer self-determines that:

The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance:

(i) Is inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant, or

(ii) Encodes only a single virtually unmodified viral coat protein. Multiple PVC-proteins could each separately meet this criterion. Chimeric PVC-proteins do not qualify.

EPA intends with the phrase ''is inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant''

to include only those PVCP-PIPs with the specified types of constructs that the 2005 SAP indicated provide a high degree of certainty that no PVC-protein would be produced. Although other types of constructs may also usually not produce any PVC-protein, EPA believes it is necessary to incorporate into its proposal a provision for an Agency review of such constructs. In such a review, EPA could evaluate the level of protein production, if any, that could occur under a variety of circumstances and environmental conditions representative of those that the plant may experience (see Unit III.E.2.ii.). EPA includes the word ''only'' and the phrase ''such that no PVC-protein is produced in the plant'' in § 174.27(c)(1)(i) to ensure that the proposed exemption encompasses only those PVCP-PIPs that the 2005 SAP indicated ''could be safely determined to have no [PVC-protein] expression regardless of plant tissue, developmental stage, environmental conditions, or exposure to virally-encoded suppressors of PTGS'' (Ref. 11). The proposed exemption criterion in § 174.27(c)(1)(i) would not be met by a PVCP-PIP when there are multiple-copy insertions in the plant if any of the copies is not in an inverted repeat orientation or lacking an initiation codon for protein synthesis.

The Agency proposes to define the term ''unmodified'' to mean, ''having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus. The Agency proposes to define the term ''virtually unmodified'' to mean, ''having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus, except for the addition of one or two amino acids at the N- and/or C-terminus other than cysteine, asparagine, serine, and threonine and/or the deletion of one or two amino acids at the N- and/or C-terminus.'' EPA's rationale for these proposed definitions and alternative proposals for defining ''virtually unmodified'' are found in the companion document published in today's **Federal Register**. The alternative proposals for virtually unmodified will also be considered as alternatives under this FIFRA proposal.

EPA is proposing to exclude more significantly modified PVC-proteins from the proposed categorical exemption by requiring that the genetic material encode ''only a single virtually unmodified viral coat protein.'' For example, PVC-proteins containing internal insertions, deletions, or amino acid substitutions would be excluded, as would be chimeric proteins that are encoded by a sequence constructed from portions of two or more different plant virus coat protein genes. EPA is proposing to exclude such PVC-proteins from the self-determining part of the exemption in response to the advice of the FIFRA SAP in October 2004 that, ''[t]here was general agreement that an allergenicity assessment[2] would be appropriate for insertions or deletions, except perhaps for terminal deletions that do not affect overall protein structure.'' Insufficient information exists at this time to allow EPA to describe *a priori* a criterion that would ensure all PVC-proteins with modifications other than those encompassed by the definition of ''virtually unmodified'' fall within the base of experience supporting the proposed exemption. At this time, it is not possible to make a categorical risk assessment finding that other types of changes are unlikely to change the characteristics of any protein produced. Thus, EPA proposes no other modifications be allowed in PVC-proteins that would meet § 174.27(c)(1).

EPA intends that multiple PVC-proteins expressed in the same plant could each separately meet the criterion in § 174.27(c)(1)(ii) but that chimeric PVC-proteins could not meet this criterion. Chimeric proteins would include PVC-proteins composed of the fusion of two (or more) whole or partial capsid proteins, as well as chimeric proteins that contain a PVC-protein fused with another, unrelated protein. The 2005 SAP concluded that such chimeric proteins could possibly have ''completely different antigenic and possibly allergenic properties compared to the properties of the individual capsid proteins'' (Ref. 11). EPA is therefore unable to conclude that such proteins would be low risk without a case-by-case review of the protein. EPA intends that multiple, distinct PVC-proteins produced, for example, from a single transgene insertion event or from multiple insertion events in the same plant, could qualify for this exemption because the Agency believes that the properties of each individual protein would be the relevant factors to consider. Some members of the 2005 SAP believed that ''EPA evaluations should consider effects of multiple constructs of PVCP-PIPs introduced in transgenic plants'' (Ref. 11). The rationale for this concern appears based in part on the potential for a synergistic effect from multiple toxins. However, PVC-proteins produced from a PVCP-PIP that could qualify for this exemption would not be expected to have any toxic mode of action that could cause such a phenomenon. The rationale for this concern appears to be also based in part on the potential for multiple PVC-proteins to ''alter 'natural' protein production in plants'' (Ref. 11). However, EPA concurs with other 2005 SAP members who ''believed that this situation was no different than is likely to occur in nature, where a plant might be infected by multiple unrelated viruses'' (Ref. 11). (See also Unit IV.E.1. in the companion document published in today's **Federal Register** for the basis for EPA's conclusion that exposure to plants with different levels of proteins elicited by pathogen attack, wounding, or stress, i.e., ''pathogenesis-related proteins,'' likely occurs normally.)

EPA believes the phrase ''an entire coat protein'' in the definition of ''virtually unmodified'' conveys that segments of PVC-proteins do not meet the criterion in § 174.27(c)(1)(ii). This limitation is based on the advice of the 2005 SAP that ''[d]etermining whether PVC-proteins containing terminal deletions, or any other modifications, are within the range of natural variation would require the development of a database of the natural variation and truncated forms of PVC-proteins that occur naturally.'' As such, EPA could more appropriately take this consideration into account under the criterion in § 174.27(c)(2)(i) which contains provisions for an Agency review (discussed below in Unit III.E.2.ii.). However, EPA is considering several alternative definitions for ''virtually unmodified,'' some of which may allow truncated PVC-proteins to meet the proposed criterion in § 174.27(c)(1)(ii). These alternatives are presented and discussed in Unit IV.E.1. of the companion document published elsewhere in today's **Federal Register**.

If the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance encodes only a single virtually unmodified viral coat protein, no novel exposures to humans or nontarget organisms are likely to occur because these PVC-proteins are essentially identical to plant viral coat proteins that are widespread in the plant kingdom, as most plants are susceptible to infection by one or more viruses. EPA is relying on this history of safe exposure to support this proposal. The Agency believes that when such a PVCP-PIP is used, the PVCP-PIP would pose low probability of risk with respect to protein production. EPA is proposing that no further data or information would be needed to evaluate this issue

[2] The concern relating to the need for an allergenicity assessment is relevant to the Agency's determinations concerning occupational exposures.

when § 174.27(c)(1) is satisfied, and therefore no Agency review would be necessary.

ii. *Proposed exemption criterion conditional on Agency determination in § 174.27(c)(2)*. The Agency acknowledges that many PVCP-PIPs may pose low risk with respect to concerns associated with protein production even though they fail to satisfy § 174.27(c)(1). EPA is proposing to review such PVCP-PIPs under slightly different factors that the Agency believes also ensure that qualifying PVCP-PIPs pose low risk with respect to concerns associated with protein production. Therefore, EPA is proposing that, under § 174.27(c)(2), a PVCP-PIP would also meet § 174.27(c) if:

The Agency determines after review that the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance:

(i) Encodes a protein that is minimally modified from a coat protein from a virus that naturally infects plants, or

(ii) Produces no protein.

EPA developed the criterion in § 174.27(c)(2) because the Agency recognizes that developers may wish to modify PVCP-PIP constructs to achieve certain product development goals such as greater efficacy, and such modifications might result in changes to the protein(s) produced. Most minor modifications to the genetic material would be unlikely to cause changes to the protein that would be significant from a human or nontarget organism perspective. Under § 174.27(c)(2) EPA may consider such modifications on a case-by-case basis. Many of the modifications are likely to produce proteins that fall within the range of natural variation of the virus. However, it is not currently possible to define clearly the range of variation of viruses in general or even of any particular virus as discussed in Unit IV.D. of the companion document published in today's **Federal Register**. Therefore, § 174.27(c)(2)(i) requires an Agency review to determine qualification.

PVCP-PIPs are known to confer resistance by two mechanisms. Resistance may be either protein-mediated, in which the level of resistance is correlated with the level of protein expression, or it may be RNA-mediated, in which the level of resistance is not correlated with the level of protein expression. (See discussion in Unit II.E.) In the case of RNA-mediated resistance, little to no PVC-protein may be produced from the PVCP-PIP. In such cases, little to no risk due to protein production would be associated with the PVCP-PIP. However, the Agency believes that the only conditions that can *a priori* indicate there will be no protein production are encompassed by the criterion in § 174.27(c)(1). Any other type of construct that may confer RNA-mediated resistance through PTGS would be reviewed by the Agency under the criterion in § 174.27(c)(2)(ii). A PVCP-PIP would meet § 174.27(c) if EPA determines that no PVC-protein is produced from the PVCP-PIP.

If protein is produced, today's proposed exemption would cover only those PVC-proteins that are not significantly different from naturally occurring plant viral coat proteins, i.e., proteins that are virtually unmodified or minimally modified. For more significantly modified PVC-proteins, the base of experience upon which EPA relies for support of the proposed exemption would not be applicable. Therefore, EPA would not be able to make the determination *a priori* as part of this proposed rule that the PVCP-PIP poses a low probability of risk to humans and the environment and will not generally cause unreasonable adverse effects on the environment even in the absence of regulatory oversight under FIFRA. However, such PVCP-PIPs may still be eligible for registration, and any significantly modified PVC-proteins could be evaluated as part of the registration review (as discussed in Unit II.G.). (For discussion of the concept of ''minimally modified'' see Unit IV.E.2. of the companion proposed exemption published in today's **Federal Register**.)

3. *Historical approaches*. EPA's current proposed approach is consistent with what EPA has always intended. EPA has never intended that any proposed exemption for PVCP-PIPs would cover those PIPs that produce proteins significantly different from those that occur naturally (November 23, 1994, 59 FR at 60524; July 19, 2001, 66 FR 37865 and 66 FR 37796).

IV. Proposed Exemption for Certain Inert Ingredients

As noted in Unit II.F. of this preamble, one of the general qualifications for exemption at § 174.21 is that ''any inert ingredient that is part of the plant-incorporated protectant is on the list codified at §§ 174.485 through 174.490.'' EPA is proposing to add several substances to § 174.486 when they are used in a PIP that is listed in 40 CFR part 174 subpart B - Exemptions and are in a plant that satisfies § 174.27(a):

- *beta*-D-glucuronidase (GUS) from *Escherichia coli* and the genetic material necessary for its production,
- neomycin phosphotransferase II (NPTII) and the genetic material necessary for its production,
- phosphomannose isomerase (PMI) and the genetic material necessary for its production,
- CP4 enolpyruvylshikimate-3-phosphate (CP4 EPSPS) and the genetic material necessary for its production,
- glyphosate oxidoreductase (GOX or GOXv247) and the genetic material necessary for its production, and
- phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production.

Below is a summary of EPA's finding that these inert ingredients present a low risk to human health and the environment; the docket for this proposed rule contains the Agency's full risk assessment in the document ''Environmental Risk Assessment of Plant-Incorporated Protectant (PIP) Inert Ingredients.'' EPA also proposes to add to subpart X the partial tetracycline resistance gene as present under the control of a bacterial promoter in papaya line 55–1.

EPA has conducted an environmental risk assessment of the PIP inert ingredient phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified plant to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in support of Dekalb's DBT 418 and Ciba Seed's Event 176 Bt corn registrations and Syngenta's COT 102 Bt cotton registration. Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 1997, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1151; 62 FR 17717, April 11, 1997). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA has conducted an environmental risk assessment of the PIP inert ingredient CP4 enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified crop to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in

support of Monsanto's MON 810 Bt Corn registration. Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 1996, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1174; 61 FR 40338, August 2, 1996). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA has conducted an environmental risk assessment of the PIP inert ingredient glyphosate oxidoreductase (GOX) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified crop to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in support of Monsanto's MON 810 Bt Corn registration. Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 1997, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1190; 62 FR 52505, October 8, 1997). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA has conducted an environmental risk assessment of the PIP inert ingredient neomycin phosphotransferase II (NPTII) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified crop to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in support of Monsanto's NewLeaf Potato and YieldGard Plus Corn registrations and is discussed in more detail in the *Bacillus thuringiensis* Plant-Incorporated Protectant and MON 863 Biopesticide Registration Action Documents (Ref. 123). Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 1994, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1134; 59 FR 49351, September 28, 1994). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA has conducted an environmental risk assessment of the *Escherichia coli*-derived PIP inert ingredient *beta*-D-glucuronidase (GUS) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified crop to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in support of Monsanto's Bollgard II Bt cotton registration and are discussed in the Bollgard II Biopesticide Registration Action Document (Ref. 124). Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 2001, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1216; 66 FR 42957, August 16, 2001). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA has conducted an environmental risk assessment of the *Escherichia coli*-derived PIP inert ingredient phosphomannose isomerase (PMI) and the genetic material necessary for its production. Topics covered in this assessment include mode of action, ecological effects, endangered species considerations, and gene flow from a modified crop to wild or weedy relatives. Data cited in this assessment were submitted to the Agency in support of Syngenta's MIR604 Bt corn registration. Ecological data and published information on the biology of this protein indicate that this PIP inert ingredient is not known to be toxic and/or pathogenic to plant or animal species. In 2004, the Agency granted a tolerance exemption for this PIP inert ingredient in all plants due to the low human health risks associated with this protein (40 CFR 180.1252; 69 FR 26770, May 14, 2004). Based on all of its assessments, EPA has determined that this inert ingredient will pose low ecological and occupational risk.

EPA believes the partial tetracycline resistance gene as present in papaya line 55–1 presents low risk to human health and the environment and could also be added to 40 CFR part 174 subpart X. No protein is expected to be produced from the gene because it is under the control of a prokaryotic promoter and is only a partial gene that is not expected to function in plants (Ref. 125). Therefore, no ecological or human health effects would be associated with this inert ingredient as found in papaya line 55–1 because it consists of only DNA. Transfer of an antibiotic resistance marker gene from plants to microorganisms in the gut or in the environment may theoretically be possible, but it is extremely unlikely (Refs. 126 and 127). In addition, because only a portion of the tetracycline resistance gene is present in papaya line 55–1, if any horizontal gene transfer of this genetic material were to occur, it would be unlikely to confer antibiotic resistance to any organism that acquired it (Ref. 125).

EPA asked the 2005 SAP to comment on the Agency's environmental risk assessment for the first six of these selectable markers. The Panel concluded that the ''antibiotic resistance marker (NPTII) and other markers (GUS and PMI) should be exempt provided they were in the plant species determined to be of low risk using criteria'' the SAP proposed as discussed in Unit III.C.2.i. (Ref. 11) and EPA relied on, as appropriate, in developing the list comprising § 174.27(a)(1). In addition, the Panel concluded that the ''herbicide markers (CP4 EPSPS, GOX/GOXv247 and PAT) should not be exempted, but rather should be considered on a case-by-case basis taking into consideration the potential that the crop plant has to become feral'' (Ref. 11). EPA notes, however, that the only crop plants that will be included on the list comprising § 174.27(a)(1) are those whose potential to become feral has been considered. Thus, EPA's inclusion of these six selectable markers in 40 CFR part 174 subpart X - List of Approved Inert Ingredients when they are used in PIPs as inert ingredients in a plant that satisfies § 174.27(a) is consistent with the 2005 SAP's recommendations regarding these inert ingredients.

EPA is also considering an alternative under which NPTII, GUS, and PMI would be exempt from FIFRA when used as inert ingredients with any exempt PIP, regardless of the plant in which they are expressed. Although the SAP recommended that they only be exempt provided they were used in a plant species determined to be of low risk based on the considerations encompassed in § 174.27(a), the Panel did not provide a rationale as to why the markers would not be considered low risk in other plants as well. Given that these markers are widespread in the environment and would be expected to confer no particular selective advantage

on any plant in the environment that might express them, the Agency knows of no rationale why this limitation would be necessary. The Agency believes that its risk assessment would support such an exemption for these inert ingredients.

EPA is also proposing a technical correction to § 174.480 to make the language consistent with the general requirements for exemption, which recognize that for some PIPs no FFDCA tolerance may be required. In such cases, it is not necessary that the inert ingredients have been exempted from FFDCA section 408 requirements.

V. Economic Analysis

Virus infection is a serious problem in agricultural production. Virtually every plant species is susceptible to infection by at least one of more than 500 known plant viruses (Ref. 6). Particular crop or weed hosts are nearly always infected by certain plant viruses under natural conditions (Ref. 103). Plant viruses create economic losses for a vast variety of crops by reducing yields and negatively affecting the quality of the crop, damaging fruits, leaves, seeds, flowers, stems, and/or roots (Refs. 103 and 128). Symptom development and vector transmission rates are affected by the environment and so can vary across locations or seasons (Ref. 103).

Virus diseases have often resulted in devastating agricultural losses, at times destroying entire plantings of crops in certain locations (Ref. 103). For example, more than 100 million citrus trees had been destroyed by citrus tristeza virus (CTV) by 1991 in citrus growing regions around the world, including California (Ref. 129). CTV is one of the most economically important viruses because of its widespread distribution, the severity of damage caused by infection, and the long life span of individual trees (Ref. 130).

Growers may need to use several control methods during a crop season in an attempt to prevent viral infection and dissemination, primarily by planting virus-free material for mechanically transmitted viruses. For vector-transmitted viruses, control measures have often focused on chemical insecticides, fungicides, and nematicides to reduce the population of vectors that transmit viruses from plant to plant. However, control of vectors is not always feasible or effective as a way to control virus transmission (Ref. 103). In another common control strategy, crops are grown in rotation with crops that the virus does not infect to reduce the virus load in the field. This method has serious limitations as well. In some cases, the development of resistant cultivars can be the only viable means of virus control. Plants developed through conventional breeding techniques offer some degree of virus resistance. However, breeding for resistance has not been successful for the majority of field crops that are severely affected by viruses (Ref. 128). In some agricultural regions, some crop species cannot be grown effectively because of the persistent presence of infected plant populations and/or potential virus vectors (Ref. 103). Contrary to traditional control measures, transgenic virus-resistant crops offer an effective means of virus protection.

This proposed rule would benefit the public by ensuring protection of human health and the environment while also reducing the cost of and time needed for regulatory review of transgenic virus-resistant crops. This proposal would also help to appropriately allocate Federal resources for risk evaluation by focusing Agency attention on those PVCP-PIPs that warrant review. This proposed rule would also benefit the industry by removing regulatory uncertainty for this class of products.

This economic analysis (EA) prepared for this proposed rule estimates the projected compliance cost for the industry under the baseline of full registration for all PVCP-PIPs and compares that to the compliance cost for the potentially affected industry under the proposed rule in order to estimate the expected savings from the regulation relief. The steps used to obtain a cost estimate for the proposed rule are summarized below.

Since the nature and timing of future development of PVCP-PIPs are unknown, the EA begins by identifying nine case studies that represent the broadest range of PVCP-PIPs that the Agency anticipates could be developed in the future. After considering the characteristics of the products that have already been marketed, characteristics of the crop plants that have been the subject of field trials for PVCP-PIPs, and knowledge of the field of genetically engineered virus-resistant crops, EPA estimated the percentage of products projected to be characterized by each case study, i.e., the ''prevalence'' of the case study. The stated prevalence represents the best estimate of the expectation of a PVCP-PIP product like the one in a specific case study being developed in the future.

For each case study, a set of data would be required of a developer in order to register the PVCP-PIP. The cost and burden of potential data requirements for each case study under the baseline are compared with the potential data requirement costs and burden under the proposed option. Using the prevalence for each case study, EPA estimated the probability of developing a PVCP-PIP product like that examined in any of the case studies in any year, given that the Agency anticipates 1.5–2.5 PVCP-PIPs being developed each year over a 10–year period. These probabilities determine the frequency and timing of development and registration of PVCP-PIPs in a model EPA designed to compute compliance cost savings.

To estimate compliance cost savings in any year, the number of PVCP-PIPs like the one developed in a given case study was multiplied by the difference between cost and burden under the proposed rule and baseline. Since the model made use of probabilities, the average of 5,000 simulations was computed for each year to represent the annual compliance cost savings for the proposed rule. Using this procedure, the estimated annual impact, based on average cost estimates per data requirement, is expected to result in a regulatory compliance cost reduction approximately within the range of $340,000 and $360,000 a year. Over a 10–year period, the annual average regulatory compliance cost reduction is expected to be approximately $350,000.

The potential exemptions under the proposed rule, as compared to the baseline under which no PVCP-PIPs are exempted, would reduce regulatory costs for the potentially affected industry and the EPA, remove regulatory uncertainty for industry, and provide important information to the public regarding the safety of exempted PVCP-PIPs. Entities that may benefit from the proposed rule and alternative options are the public, companies that develop and market PVCP-PIPs (applicants and/or registrants), farmers, and the environment. However, potential future benefits to these entities are difficult to quantify due to data limitations and uncertain market conditions. In addition, considerable difficulty exists in quantitatively evaluating non-market benefits, such as reduced environmental and human health risks, consistency of regulation, reduced regulatory uncertainty, and improvements in public perception of biotechnology products.

VI. Preliminary Statutory Finding

A. What Risk Assessment Methodology did EPA use for this Proposed Rule?

Generally, when EPA assesses the risks caused by the use of a pesticide, it considers both the potential hazard that the pesticide poses to the environment and the potential for

exposure to the pesticide due to its use. For most pesticides (e.g., chemical pesticides), EPA relies on data generated by laboratory testing using representative animal models to estimate hazard endpoints. To develop exposure estimates the Agency evaluates other information including product characterization data, proposed use patterns, and information generated from mathematical models. Exposure and hazard estimates are combined to quantify the potential risk associated with the pesticide's use. The data requirements describing the types of information to be generated and other guidance for assessing risk are detailed in 40 CFR part 158.

The questions posed as part of the risk assessment in evaluating most pesticides (e.g., biological or chemical pesticides) can also be posed for the PVCP-PIPs that are exempted in this proposed action, and 40 CFR part 158 can be used as guidance. EPA adopted an approach for evaluating the potential risks of PVCP-PIPs that is consistent with the unique characteristics of pesticides produced and used in a living plant and the scientific knowledge and experience accumulated on these substances.

To address the hazard endpoints described in 40 CFR part 158 for the PVCP-PIPs that qualify for this proposed exemption, EPA relied on a very large body of information in the public literature that was developed through many decades of testing and observation. EPA thus did not need to rely on animal model testing for assessing risk as it would for most other pesticides (e.g., chemical pesticides) where specific hazard data are lacking. In addition, PIPs are produced within the living plant, and the pesticidal substance is used in situ in the plant. Exposure to PVCP-PIPs is therefore limited relative to exposure to chemical pesticides that are applied broadly in the environment, e.g., through aerial application.

1. *Large body of knowledge and experience exists.* Typically, in assessing a pesticide for environmental risk, EPA considers data fulfilling the information requirements posed in 40 CFR part 158 to evaluate the potential effect of the pesticide on birds, mammals, freshwater fish and invertebrates, estuarine and marine animals, and nontarget plants and insects (e.g., predators, parasites, and pollinators). For most pesticides, this information must be generated using animal models. To address these same questions for the PVCP-PIPs that are the subject of this proposed exemption, EPA was able to rely on a long history of hundreds, if not thousands of years of natural exposure to plant virus coat proteins by nontarget organisms. EPA relies on these experiences and the scientific literature generated by a century of food safety studies (Refs. 131 and 132) to assess the PVCP-PIPs that are the subject of these exemptions.

EPA also took into account the large and varied information base available in the public scientific literature from a number of disciplines including plant genetics, plant physiology, plant virology, weed science, molecular biology, biochemistry, ecology, and plant breeding. For example, the Agency used experimental data derived from the science of plant pathology to characterize the pest resistance mechanisms in plants (Ref. 56) and relied on the scientific knowledge base of plant virology and virus ecology to evaluate how plant viruses interact with each other and with the plant during infection (Ref. 60).

2. *PVCP-PIPs are produced within the living plant, and the pesticidal substance is used in situ in the plant, affecting the exposure paradigm.* EPA used information from the fields of plant pathology, biochemistry, microbial ecology, and ecology in considering all aspects of risk, including exposure. PVCP-PIPs are produced within the living plant itself, and the pesticidal substance is used *in situ* in the plant to protect against pests, in contrast to most other pesticides, which must be applied to or near the plant. Because a PVCP-PIP is produced and used within the plant, physiological constraints limit the amount of pesticidal substance produced by the plant. Regardless of the tissues containing the PVCP-PIP or the level at which PVC-protein is expressed, the PVCP-PIP, including any PVC-protein, is contained within the plant parts. Therefore, the routes by which other organisms may be exposed to the PVCP-PIP may be more limited, e.g., dietary exposure is likely to be the predominant route of exposure, and physical contact with the plant or plant parts will generally be necessary for exposure to occur.

The PVCP-PIPs exempted by this proposed rule are biotic and are subject to the processes of biodegradation and decay that all such materials undergo (Ref. 133). Biotic materials are broken down to constituent parts through the enzymatic processes of living organisms, and these constituent parts are used as building blocks during growth of other biotic substances. In addition, PVCP-PIPs are biodegradable to their constituent elements through catabolism by living organisms. Because of their biodegradable nature, PVCP-PIPs do not bioaccumulate (i.e., build up in tissues because the body is unable to either break the substance down or eliminate it) or biomagnify (i.e., progressively build up in successive trophic levels because it bioaccumulates in the bodies of organisms lower in the food chain). Because of these characteristics, the potential for new exposures to occur beyond direct physical exposures to the plant or plant parts is limited.

A question directly affecting the exposure component of the risk assessment that has no equivalent in the assessment of more traditional pesticides (e.g., chemical pesticides) must be posed for PIPs. Because PIPs are produced and used in the living plant, the possibility that the ability to produce a PIP may be transferred by outcrossing and hybridization from the crop plant to a wild or weedy relative was considered. A large volume of information is available in the public literature to assess the risks of gene flow generally (Refs. 19 and 134) and for PVCP-PIPs in particular (Refs. 12, 32, 36, 135, 136, 137, 138, 139, and 140).

B. Exemption Determination for PVCP-PIPs, Including Certain Inert Ingredients

EPA preliminarily concludes that PVCP-PIPs that meet the criteria specified in this proposed action warrant exemption under FIFRA section 25(b)(2). The use of PVCP-PIPs that meet the criteria in 40 CFR 174.21, including the criteria proposed in this **Federal Register** to be inserted at 40 CFR 174.27 poses a low probability of risk to the environment and is not likely to cause unreasonable adverse effects in the absence of regulatory oversight. EPA bases this preliminary conclusion upon an evaluation of the potential risks that use of PVCP-PIPs qualifying for this exemption would reasonably pose to man and the environment, and upon an evaluation of whether their use causes unreasonable adverse effects. EPA preliminarily concludes that PVCP-PIPs qualifying for this exemption pose a low probability of risk to the environment as demonstrated by information from the fields of plant genetics, plant physiology, plant virology, weed science, molecular biology, biochemistry, ecology, and plant breeding; from many years of experience growing and consuming plants that contain coat proteins from plant viruses; and from Agency knowledge about horticultural and agricultural practices. EPA also believes that use of these plant-incorporated protectants in food is safe under the FFDCA section 408 standard as explained in the preamble

to this document and the companion document published elsewhere in this issue of the **Federal Register** exempting residues of the PVC-protein portion of a PVCP-PIP.

EPA believes that PVCP-PIPs that meet the criteria in 40 CFR 174.21, including the criteria proposed in this **Federal Register** to be added at 40 CFR § 174.27, are also not likely to cause unreasonable adverse effects, even in the absence of regulatory oversight. As a result, EPA concludes that PVCP-PIPs qualifying for this exemption do not cause any unreasonable adverse effects with respect to human dietary risk. Taking into account the economic, social, and environmental costs and benefits of the use of such products, as discussed in the preamble and associated Economic Analysis (found in the docket for this rulemaking), EPA believes that the low levels of risks that such products present do not justify the cost of regulating such products. Note that products that qualify for this exemption would remain subject to the requirement for submission of information regarding adverse effects under 40 CFR 174.71. Even though EPA believes the probability is very low that risks would arise with the PVCP-PIPs qualifying for this exemption, the adverse effects reporting requirement will alert the Agency should any such rare circumstances occur. EPA could then address such instances, as appropriate, under FIFRA.

VII. Request for Comment

EPA requests comment on whether the Agency has appropriately identified in this proposed exemption those PVCP-PIPs that are of a nature not requiring regulation under FIFRA. In particular, the Agency requests comment on the following specific issues:

1. EPA requests comment on whether additional plants could be appropriately included in the list of plants comprising proposed § 174.27(a)(1) because they would present low risk with respect to concerns associated with weediness of the plant itself and any wild or weedy relatives of the plant if it were to contain any PVCP-PIP. For example, the 2004 SAP identified the following plants that are not included in proposed § 174.27(a)(1): almond (*Prunus communis*), apricot (*Prunus armeniaca*), cape daisy (*Osteospermum* spp.), chrysanthemum (*Dendranthema* spp.), celery (*Apium graveolens*), eggplant (*Solanum melongena*), geranium (*Pelargonium* spp.), hyacinth (*Hyacinthus* spp.), guava (*Psidium guajava*), kiwi (*Actinidia* spp.), nectarine and peach (*Prunus persica*), okra (*Abelmoschus esculentus*), olive (*Olea europaea*), parsley (*Petroselinum crispum*), petunia (*Petunia* spp.), pistachio (*Pistacia vera*), plum (*Prunus domestica*), spinach (*Spinacia oleracea*), taro (*Colocasia esculenta*), tomato (*Solanum lycopersicum*), watermelon (*Citrullus lanatus*), and wishbone flower (*Torenia* spp.).

EPA would be particularly interested in information about these plants or others that addresses the questions in Unit III.C.2.i. that EPA posed to crop experts as part of its evaluation as to whether specific species should be included on the list. In some cases, EPA has already consulted with one or more experts for these plants, but the Agency does not believe it has the information necessary to draw a conclusion for these plants. Given the reliance on expert opinion to make these determinations, EPA would like to have responses from at least three experts for any given crop before including it on the list at § 174.27(a)(1). In other cases, EPA completed at least three consultations, but the Agency received information from at least one expert suggesting that the plant may not meet the low risk standard for inclusion in the § 174.27(a)(1) list, e.g., because of questions about the formation of viable hybrids in nature with wild or weedy relatives or questions about the propensity of the crop to naturalize. EPA describes its analyses in the following paragraphs and requests assistance from the public on the issues raised.

EPA is inclined to include almond (*Prunus communis*) on the list in § 174.27(a)(1) on the basis of information received from expert consultations. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to introgress into a population of a wild or weedy relative or a naturalized population of the species and what effect such introgression might have. Specifically, the experts indicated that natural hybrids may be able to form with some other stone fruit trees (Ref. 42). However, if such trees are likely to be found in commercial cultivation, natural hybrids would not necessarily be expected in areas outside of managed orchards. Regarding whether almond is a weedy species, both experts mentioned that almond forms feral populations. However, they have not usually required weed management activity because ''the trees are infrequent and tend to be seen as beneficial'' (Ref. 42). One expert said, ''Almond is not highly susceptible to viruses affecting other Prunus tree crop species. Thus virus resistance is not a major determinate of feral almond fitness in current environments.... Thus, it is likely that transgenic resistance would not greatly benefit either commercial or feral almonds'' (Ref. 42).

EPA is inclined to include amaryllis (*Hippeastrum* spp.) on the list in § 174.27(a)(1) on the basis of information received from consultations with amaryllis experts that EPA conducted upon recommendation from other experts in flower breeding. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the weedy characteristics of amaryllis and the potential for gene exchange between feral and cultivated populations. Two experts indicated that there are no wild or weedy relatives in the United States with which amaryllis can form viable hybrids in nature, although one expert said, ''*Hippeastrum puniceum* (Lam.) Kuntze is naturalized in Puerto Rico, the Virgin Islands, Louisiana and Hawaii. *Hippeastrum puniceum* is a diploid species that is occasionally used in breeding programs. In controlled crosses, it will breed with other diploid species, and is probably represented in modern *Hippeastrum* cultivars. However, most modern *Hippeastrum* cultivars available in the florist and greenhouse trade are complex, tetraploid hybrids that are difficult to backcross to *H. puniceum*'' (Ref. 42). One expert believed that no species in the genus are known to become feral or easily spread into non-crop areas. However, the others noted that this occasionally occurs without requiring weed management activity. One said, ''Hippeastrum puniceum may have been introduced into Puerto Rico, possibly during pre-Colombian times, and it has since sparingly naturalized.... Spread is slow and minimal and has not required management activity'' (Ref. 42). Another said, ''Plants generally naturalize in disturbed areas along roadsides and irrigation ditches. The species is self-incompatible, but can form seed in naturalized settings. The plants also reproduce asexually via off-sets. Long distance dispersal appears minimal. *Hippeastrum puniceum* is considered a low-risk introduced plant in Hawaii and appears that it does not require active weed-management'' (Ref. 42). All three experts agreed that it was unlikely acquisition of virus resistance would cause amaryllis to become feral or easily spread into non-crop areas in the United States. For example, one expert said, ''*Hippeastrum* has been grown commercial outdoors since the early 1900's in semi-tropical areas of the US (*Hippeastrum* is not winter-hardy).

There has not been a single record of any plants escaping and becoming feral. There is no reason to believe that acquiring transgenic resistance to one or more viruses would increase the ability of plants to become feral or easily spread into non-crop areas'' (Ref. 42).

EPA is inclined to include apricot (*Prunus armeniaca*) on the list in § 174.27(a)(1) on the basis of information received from expert consultations. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to introgress into a population of a wild or weedy relative or a naturalized population of the species. Specifically, two experts indicated that apricot may be able to cross with plum species because ''[i]f planted in close proximity apricot can be crossed by bees to Japanese plums. That suggests the same could happen with native US plum species, of which there are many in the eastern US'' (Ref. 42). However, both experts suggested that the frequency of hybrid production would be extremely low. Two experts indicated that apricot is not known to become feral or easily spread into non-crop areas, while the third expert said that he has ''seen rare plants in [Michigan] that are feral or left-over homeowner trees. They did not appear to spread as the big seeds mostly drop under the trees and seem not very competitive compared to the weeds'' (Ref. 42). All of the experts agreed that acquisition of virus resistance would be unlikely to change apricot's propensity to become feral. According to one expert, ''It is not likely that this would occur because climatic conditions and the occurrence of fungal and bacterial diseases are more limiting than the viruses'' (Ref. 42).

EPA believes that more information about cape daisy (*Osteospermum* spp.) is needed to address issues raised by expert consultation. EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to enhance the potential of species in this genus to naturalize. One expert indicated, ''*Osteospermum fruticosum* is a low-risk naturalized plant in Hawaii, and is also found, along with *O. ecklonis*, in California. Other *Osteospermum* species have naturalized in Australia and New Zealand. The genus is endemic to the Cape Floristic Region of southern Africa which has a Mediterranean climate. Thus, there is potential for more species of *Osteospermum* to naturalize in California which, like Australia and New Zealand, has a Mediterranean climate.... Transgenic or not, *Osteosperum* [sic] has potential to further naturalize in Mediterranean climates and needs further monitoring for invasive potential in these areas'' (Ref. 42). However, the other two experts indicated that it was unlikely that virus resistance would cause cape daisy to become feral or easily spread into non-crop areas. One said, ''Other factors are much more likely to limit its invasive potential, such as available moisture, presence of competing vegetation, and predation by insects and vertebrates. Viruses do not appear to be limiting its spread'' (Ref. 42). The other expert said, ''Viral resistance could conceivably increase fecundity and spread, but there is no data to confirm or refute the possibility'' (Ref. 42).

EPA is inclined to include chrysanthemum (*Dendranthema* spp.) on the list in § 174.27(a)(1) on the basis of information received from consultations with two chrysanthemum experts. These experts indicated that there are no wild or weedy relatives in the United States with which commercial chrysanthemum can form viable hybrids in nature. One expert believed that no species in the genus are known to become feral or easily spread into non-crop areas, while the other noted that this has occurred rarely in California, Ohio, Pennsylvania, and Massachusetts. Nevertheless, these populations have not required weed management activity because they ''have remained small consisting of only a few plants'' (Ref. 42). Both experts believed it unlikely that acquired virus resistance could lead to commercial chrysanthemum becoming feral or easily spreading into non-crop areas. One expert said, ''Plants in the genus *Dendranthema* are generally not easily propagated by seed, and are vegatatively [sic] propagated by cuttings or division. They do not compete well with other plants and do not persist in untended garden situations, and would certainly not do so in non-crop areas'' (Ref. 42).

EPA has received one response from an eggplant expert suggesting that eggplant (*Solanum melongena*) meets the requirements for inclusion on the list in § 174.27(a)(1). This consultation indicates that eggplant meets the three conditions outlined above by the SAP: it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make eggplant weedy or invasive. The expert said, ''Similar to other species where wild relatives have been utilized to enhance the cultivated form of the crop, genes for improved fitness are derived from the wild relative. Neither the disease resistant wild relative nor the improved cultivars have shown a propensity to become feral'' (Ref. 42). EPA is seeking public comment on this determination because the Agency desires a more robust response base.

EPA believes that more information about geranium (*Pelargonium* spp.) is needed to address issues raised by expert consultation. EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to spread to a wild or weedy population in the United States or enhance the potential of species in this genus to naturalize. Regarding the potential for spread to a wild or weedy population, two experts indicated that species within this genus do not form viable hybrids in nature with wild or weedy relatives in the United States, but a third expert said, ''In the wild, *P. cucullatum* will hybridize with *P. betulinum* (L.) L'Her. and *P. patulum* Jacq. *Pelargonium grandiflorum* forms natural hybrids with *P. sublignosum* Knuth. The extent to which these hybridizations and other hybridizations occur is not well known'' (Ref. 42). Regarding the weedy tendencies of this genus, one expert indicated that ''nine species are reported as naturalized or persistent in California... but most occupy disturbed sites near cultivated or urbanized areas'' (Ref. 42). Another expert said, ''It seems possible that in Mediterranean climates Pelargonium could become a weed problem'' (Ref. 42). Two other experts thought that acquisition of virus resistance would not affect the weedy tendencies of this genus. One said, ''*Pelargonium* species are notoriously poor seed producers and are all also native to Africa, particularly South Africa. They have specialized ecological niches that would not easily be available anywhere in the U.S. or its territories. California is the most likely place where this could happen, and no incidence of an adventive *Pelargonium* has ever been reported. Viral resistance would not mitigate these factors that prevent adventive establishment'' (Ref. 42).

EPA is inclined to include hyacinth (*Hyacinthus* spp.) on the list in § 174.27(a)(1) on the basis of information received from consultations with hyacinth experts. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for hyacinth to naturalize. Three experts consulted indicated that this genus does not form viable hybrids in nature with

wild or weedy relatives in the United States. Two experts indicated that there are no naturalized species of *Hyacinthus* in the United States, although a third said, ''*Hyacinthus orientalis* has been reported as naturalized in the Blackland Prairies of Texas,'' but details were not available (Ref. 42). All three experts agreed that acquired virus resistance is unlikely to make hyacinth become feral or spread into non-crop areas.

On the basis of expert consultation, EPA has concluded that guava (*Psidium guajava*) does not meet the low risk standard needed for inclusion on the § 174.27(a)(1) list. Two experts indicated that more research is needed to establish the potential for outcrossing with wild or weedy relatives. All three experts reported that guava is known to become feral or easily spread into non-crop areas in the United States. One expert stated, ''Guava is a vigorous, common, weed in both warm to cool climates. It would likely give this plant additional competitive advantage with transgenic resistance to viruses'' (Ref. 42). However, another expert believed that ''[g]uava is easily spread without having transgenic resistance. It does not appear that containing resistance to one or more virus [sic] would enhance its ability to become feral'' (Ref. 42). EPA requests commenters who believe guava would be appropriate to include on the list in § 174.27(a)(1) specifically to address whether there are wild or weedy relatives with which guava could form viable hybrids in nature in the United States (including Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa) and to address the concern that guava is a weedy species and acquisition of virus resistance could exacerbate these tendencies. Please provide literature citations or other evidence to support any claims contrary to EPA's expert consultations.

EPA believes that more information about lily (*Lilium* spp.) is needed to address issues raised by expert consultation conducted after recommendation from other flower experts. EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for lily to become feral or spread into non-crop areas and the impact that acquired virus resistance might have on this potential. The experts agreed that in the United States the likelihood of a species in the genus *Lilium* forming viable hybrids in nature with a wild or weedy relative was very small given that lilies do not cross readily. ''This is especially true for the hybrids that are adapted or selected for the intensive greenhouse or irrigated gardens' environment. These lilies do not form successful colonies outside these specific environments. The chance that genes will be transferred from gardens to wild populations is negligible'' (Ref. 42). However, regarding the weedy tendencies of this genus, one expert said ''Several species of Asian or European origin are sporadically naturalized following escape from cultivation, but none strays far or is widespread or common enough to be considered a pest.... *Lilium longiflorum* (Easter lily; Japan) has been recorded from Utah and Florida'' (Ref. 42). Another expert said, ''*Lilium* [*formosanum*] (Taiwan lily) has been known to invade natural habitats in Northern and Eastern Australia.... Caution would be advised in introducing L. [*formosanum*] into... the US'' (Ref. 42). Two experts believed it unlikely that acquired virus resistance would affect the likelihood of lilies becoming feral, although a third said, ''Virus resistance might increase the speed and degree with which these exotic species might naturalize'' (Ref. 42).

EPA is inclined to include nectarine and peach (*Prunus persica*) on the list in § 174.27(a)(1) on the basis of information received from expert consultations. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to introgress into a population of a wild or weedy relative or a naturalized population of the species and what effect such introgression might have. Specifically, the experts indicated that natural hybrids may be able to form with some other stone fruit trees (Ref. 42). However, if such trees are likely to be found in commercial cultivation, natural hybrids would not necessarily be expected in areas outside of managed orchards. Regarding whether *Prunus persica* is a weedy species, three of the four experts mentioned that nectarines and peaches are able to form feral populations (Ref. 42). Nevertheless, three of the four experts indicated that they believed it would be unlikely that *Prunus persica's* weedy tendencies, if any, would be exacerbated if it acquired transgenic resistance to one or more viruses. One expert said, ''Generally the viruses are not the limiting factor to the establishment of feral peaches. The limiting factors are fungal and bacterial diseases that kill the plants before they can reproduce'' (Ref. 42). The fourth expert said, ''I would expect that the acquisition of virus resistance would enhance the spread of feral populations but would suggest that other causes of death, such as peach tree short life, bacterial canker and Armillaria Root Rot, are likely to be a more significant limitation to the spread and longevity of a feral nectarine tree'' (Ref. 42).

EPA believes that more information about olive (*Olea europaea*) is needed to address issues raised during expert consultation. Two experts indicated that hybridization with a wild or weedy relative has not been documented in the United States (Ref. 42). Both of these experts indicated that olive can naturalize. However, they disagreed about the frequency with which this is likely to occur. One expert suggested olive frequently forms reproducing and sustaining populations in non-crop areas and that it was ''highly likely'' that olive would become feral or easily spread into non-crop areas if it acquired transgenic resistance to one or more viruses because ''*O. europaea* seeds are very viable and dispersed by rodents'' (Ref. 42). However, another said, ''It is highly unlikely that olives would become strongly feral or widely spread because the seeds are infrequently spread far from the tree, have a low reproduction rate due to poor seed germination and have a high rate of feral seedling mortality. Further, as a slow growing tree olives do not spread rapidly'' (Ref. 42). The 2005 SAP also commented on including olives in the list of plants in § 174.27(a)(1). They noted olives have reportedly formed ''feral olive infestations in the Channel Islands National Park, and in oak woodlands and forest on Sonoma Valley and Davis, CA. In California, olive is 'considered an invasive exotic' that 'compete[s] with native flora' (personal communication)'' (Ref. 42). EPA believes that before olive could be added to the list of plants in § 174.27(a)(1), the Agency would need information to resolve the question of how weedy olive is in the United States and the effect virus resistance would have on any feral populations of olive that could acquire a PVCP-PIP from cultivated olive.

EPA has received one response from a parsley expert suggesting that parsley (*Petroselinum crispum*) meets the requirements for inclusion on the list in § 174.27(a)(1). This consultation indicates that parsley meets the three conditions outlined above by the SAP: it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make parsley weedy or invasive. The breeder noted that parsley

could form viable hybrids with feral populations of parsley, but ''parsley populations are generally quite short-lived away from cultivation and typically are not self-sustaining'' (Ref. 42). He also noted, ''I would not expect parsley to become more easily spread with the acquisition of virus resistance. Although I'm aware that parsley is a host to celery mosaic virus and carrot motley dwarf, I have not known these viruses to be common limiting factors in parsley growth or reproduction, at least not here at our genebank in Iowa. Fungal diseases and insects are much more important'' (Ref. 42). EPA is seeking public comment on this determination because the Agency desires a more robust response base.

EPA is inclined to include petunia (*Petunia* spp.) on the list in § 174.27(a)(1) on the basis of information received from consultations with petunia experts. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the weedy characteristics of petunia and the likelihood that acquired virus resistance could cause petunia to become feral or easily spread into non-crop areas. The experts indicated that this genus does not form viable hybrids in nature with wild or weedy relatives in the United States. However, two of the three experts indicated that petunia has formed reproducing and sustaining populations in non-crop areas while noting that such populations have not required weed management activity. All three experts indicated that acquired virus resistance is unlikely to change the status quo. However, one noted that, ''as viruses affect petunia vigor, resistance might conceivably increase the odds'' (Ref. 42).

EPA is inclined to include pistachio (*Pistacia vera*) on the list in 174.27(a)(1) on the basis of information received from two expert consultations. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to introgress into a population of a wild or weedy relative or a naturalized population of the species and what the impact of acquired virus resistance is likely to be. Specifically, the experts indicated several crosses have been reported in the literature, suggesting ''that potentially *P. vera* genes can eventually be transmitted to other species in the form of gene flow.'' However, hybrids are only rarely formed as ''they are isolated phenologically....'' Nevertheless, one expert also indicated, ''There are a lot of unknowns in the phenology and cross-compatibility of different species of pistachio'' (Ref. 42). Both experts indicated that ferality in pistachio is rare. One suggested it was not possible to say what the likelihood would be that pistachio would become feral or easily spread into non-crop areas if it acquired transgenic virus resistance. However the other said, ''It is very unlikely pistachio would be widely feral as the primary method of spread, drop from the tree, results in a large percentage (>95%) of the nuts degrading, so they do not sprout. Further, the nuts do not go a long distance when they drop, localizing spread if sprouting does occur. Finally, if birds do remove a nut with a viable embryo from the tree they generally destroy it by eating...'' (Ref. 42).

EPA is inclined to include plum (*Prunus domestica*) on the list in § 174.27(a)(1) on the basis of information received from expert consultations. However, EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to introgress into a population of a wild or weedy relative or a naturalized population of the species. Specifically, the experts indicated that several native plum species occur in the United States. However, one indicated that because ''*P. domestica* is a hexaploid, it would not cross with native *Prunus* plum species, which are all diploid'' (Ref. 42). In addition, if any hybrids between cultivated plum and wild American plum species did occur, they ''would not be fertile because of the chromosome number difference.'' EPA thus believes that the risk of introgressing a PVCP-PIP into a wild or weedy population through gene transfer in the United States is very low. Regarding whether plum is a weedy species, one expert mentioned that although he had not personally observed it, he ''heard from others that domestica... [is] found naturalized particularly in New England and Oregon. Some of these species tend to be easily spread by root suckers, and are better able to compete as weeds. Likely they only survive on roadsides and unmanaged areas, and could be easily killed if desired'' (Ref. 42). Nevertheless, all three of the experts indicated that they believed it would be unlikely that plum's weedy tendencies, if any, would be exacerbated if it acquired transgenic resistance to one or more viruses. According to one expert, ''I doubt viruses are the only thing which restricts domestica from spreading more than it already has'' (Ref. 42). According to another, ''Currently virus diseases are not the most important limiting diseases for plum in the U.S. Other fungal and bacterial diseases are the limiting factors and cause death of uncared for commercial plums. Therefore transgenic plums with virus resistance would still be very susceptible to these limiting fungal and bacterial diseases'' (Ref. 42).

EPA has received one response from a spinach expert suggesting that spinach (*Spinacia oleracea*) meets the requirements for inclusion on the list in § 174.27(a)(1). This consultation indicated that spinach meets the three conditions outlined above by the SAP: it does not have wild or weedy relatives in the United States with which it can form viable hybrids in nature, it is not currently weedy or invasive in the United States, and there is no reason to believe that acquisition of virus resistance would make spinach weedy or invasive. The expert noted, ''Transgenic viral resistance alone probably would not make spinach survive wild conditions, because there are other fungus (e.g. downy mildew, Stemphylium leaf spot) diseases and bacterial diseases (e.g. bacterial leaf spot), as well as drought resistance and competing ability issues'' (Ref. 42). EPA is seeking public comment on this determination because the Agency desires a more robust response base.

EPA believes that more information about taro (*Colocasia esculenta*) is needed to address issues raised by expert consultation. For example, although experts knew of no weedy relatives with which taro might cross, ''crossing is theoretically possible among all of the taros'' (Ref. 42). One expert indicated that ''taro can flower naturally in places such as Kula in Maui, Hawaii. The climate there allows taro to flower naturally, whereas in other places it is often necessary to induce flowering with hormone applications. Furthermore, hybrids made by cross-fertilization are viable. It is entirely possible for taro to survive in the wild in tropical and subtropical climates. Most taros would succumb because taro has been cultivated for so long that it is mostly dependent on humans to compete with many weeds. By itself it is almost always out-competed by weeds and dies out. But theoretically it can survive, it can cross-pollinate and form viable progeny'' (Ref. 42). Regarding whether taro is known to become feral or easily spread in non-crop areas, one expert said, ''YES, but only in favorable conditions of adequate warmth and moisture.'' Another expert indicated that ''taro is considered an invasive species in certain places (Florida)'' (Ref. 42). Regarding whether acquired transgenic resistance to one or more viruses could change taro in this

respect, the experts disagreed. One expert said, ''It is highly unlikely that taro with acquired transgenic resistance would spread to non-crop areas because the probability of crossing is extremely small. Through vegetative propagation it will require man intervention just as non-transgenic plants.'' Another expert said, ''Taro has many pests, including viruses, that restricts [sic] its ability to compete with more weedy plant species. Resistance to any of these pests would increase its competitiveness but this is not likely to turn taro into a weed problem.'' However, the third expert said, ''With resistance to one or more virus diseases, taro would become hardier. That is the reason for breeders to go to the trouble of developing disease-resistant plants. A hardier taro is more likely to be successful and survive as an escaped cultivated species. It has already been seen that taro has become feral in certain parts of Florida. With added resistance, it would be more likely to survive in the wild, provided that resistance gives it some advantage. In other words, if the virus disease is important, resistance is valuable. In Thailand, the taro plants that one can find along roadsides (feral) possess a high degree of resistance to taro leaf blight, the most destructive disease of cultivated taro there. Those that don't possess resistance don't stand much of a chance to survive on their own'' (Ref. 42). EPA believes that before taro could be added to the list of plants in § 174.27(a)(1), the Agency would need information to evaluate the likelihood that feral populations of taro could acquire a PVCP-PIP from cultivated taro and to evaluate whether acquisition of virus resistance is likely to increase taro's likelihood of forming feral populations.

EPA believes that more information about tomato (*Solanum lycopersicum*) is needed to address issues raised by several experts that EPA consulted. For example, three of four experts indicated that tomato is able to form viable hybrids in nature in the United States with its putative progenitor *Solanum lycopersicum* var. *cerasiforme*. These experts indicated the hybrids formed are fertile, self-compatible, and freely intercross due to highly compatible phenology. However, a third expert indicated that ''[a]lthough crosses can occur between wild species and cultivated tomato, usually with human intervention, the direction of the cross is such that the wild species has to be the male parent.... If the cultivated tomato has the transgene, transfer to wild species via pollen will not happen'' (Ref. 42). EPA is not however interested solely in whether transfer occurs via pollen, but whether a transgene could introgress into a wild population through a hybrid intermediate. Three of four experts also indicated that tomato is able to form feral populations in the United States (including Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa), although one expert pointed out that neither virus-resistant cultivars nor resistant wild relatives have demonstrated a greater propensity to become feral, suggesting that acquisition of a PVCP-PIP may not exacerbate whatever weedy tendencies exist in tomato. However, another expert suggested that this question would have to be tested in the field under controlled conditions. EPA believes that before tomato could be added to the list of plants in § 174.27(a)(1), the Agency would need information to evaluate the effect of virus resistance on any wild or weedy populations of tomato that could acquire a PVCP-PIP from cultivated tomato and to evaluate whether acquisition of virus resistance is likely to exacerbate tomato's weedy tendencies.

EPA believes that more information about watermelon (*Citrullus lanatus*) is needed to address issues raised by expert consultation. For example, experts indicated that watermelon is able to cross with *C. lanatus* var. *citroides*. Moreover, one expert indicated hybrids made by cross-fertilization are sexually fertile and demonstrate ''[m]ore vigor compared with cultivated watermelon (*C. lanatus* var. *lanatus*)'' (Ref. 42). Regarding whether watermelon is known to become feral or easily spread in non-crop areas, one expert indicated that escaped plants are able to form reproducing and sustaining populations in non-crop areas, although this occurs rarely and has not required weed management activity outside of crop areas (Ref. 42). Regarding whether acquired transgenic resistance to one or more viruses could change watermelon in this respect, one expert indicated this was ''[u]nlikely. Watermelons have few viruses that kill the plant or decrease its reproductive activity. Therefore, gaining virus resistance will not likely increase it's [sic] reproductive success in feral populations'' (Ref. 42). Another expert said, ''Virus pressure would likely be far less in feral populations than in cultivated fields due to differences in time of germination, rate of growth, population density, [and] reduced numbers of aphid vectors'' (Ref. 42). EPA believes that before watermelon could be added to the list of plants in § 174.27(a)(1), the Agency would need information to evaluate the likelihood that wild populations of *C. lanatus* var. *citroides* or feral populations of *C. lanatus* var. *lanatus* could acquire a PVCP-PIP from cultivated watermelon and what effect this acquisition might have.

EPA believes that more information about wishbone flower (*Torenia* spp.) is needed to address issues raised by expert consultation. EPA is seeking any information from the public that would enable the Agency to complete its assessment of the potential for a PVCP-PIP to enhance the potential of species in this genus to naturalize. All three experts consulted indicated that *Torenia* species do not form viable hybrids in nature with wild or weedy relatives in the United States. However, all indicated that *Torenia* has naturalized in certain areas of the United States. One expert said, ''*Torenia fournieri* has been reported to naturalize by seed in Florida and Louisiana, but it is not clear to what extent. I personally have observed re-seeding in garden settings. Given the rising popularity of Torenia in American horticulture, there is probable cause for concern in the deep south, California and Hawaii. However, the species in cultivation are heat sensitive and moisture-demanding, which would probably limit the extent to which they can naturalize'' (Ref. 42). Expert consultations also suggest that not enough information is known about the potential of virus resistance to affect the plant's weedy tendencies. One expert said, ''I do not know to what extent viruses impact *Torenia fournieri*. It is conceivable that viral resistance could increase fecundity'' (Ref. 42).

EPA is not proposing to include celery (*Apium graveolens*), kiwi (*Actinidia* spp.), or okra (*Abelmoschus esculentus*) on the list in § 174.27(a) because the Agency was unable to complete any expert consultations on these crops. EPA is therefore seeking information from the public to address whether such crops could qualify for inclusion on the list.

EPA also requests comment on the weediness potential of squash (*Cucurbita pepo*) and any wild or weedy relatives in the United States that could acquire a PVCP-PIP from cultivated squash through gene flow.

2. EPA requests comment on the Agency's options for the weediness criterion in § 174.27(a)(2) discussed in Unit III.C.2.iii. Specifically, the Agency is considering whether it is more appropriate to evaluate the potential for a crop to form ''viable hybrids'' or

''viable, fertile hybrids'' in nature with a wild or weedy relative.

In addition, EPA is considering whether it is necessary to evaluate whether the plant containing the PIP is unlikely to establish weedy or invasive populations outside of agricultural fields in the United States even if the plant contains a PVCP-PIP, assuming that the plant has no wild or weedy relatives in the United States with which it can form viable hybrids in nature and it is not a weedy or invasive species outside of agricultural fields in the United States.

EPA also requests comment on language for the criterion in § 174.27(a)(2) (e.g., such as under option four) that would allow EPA to broadly consider the effect that virus resistance might have on wild or weedy plant populations that could acquire the PVCP-PIP. Under such an approach, the individual determinations that the Agency would make would likely require data to be generated that would not normally occur as a routine part of product development (but may be developed for a review by USDA/APHIS). Such determinations are likely to involve similar amounts of effort as registration reviews, but they would provide a means whereby a PVCP-PIP could be exempted even if used in a plant that has wild or weedy relatives in the United States. The Agency requests commenters to indicate how controversial individual determinations using such language as under option 4 are likely to be, as the Agency would like to have an exemption procedure that requires only one public notice (see Unit III.A.2.).

3. EPA requests comment on the merits of incorporating the use of biocontainment and/or bioconfinement techniques into § 174.27(a), such that PVCP-PIPs deployed in tandem with such technology could be determined to meet the weediness criterion. Please see the discussion of this option in Unit III.C.3., which articulates several issues associated with such an option and suggests regulatory language that might be used.

4. EPA requests comment on the Agency's use of the term ''weedy.'' EPA uses the term in two different contexts: in ''wild or weedy relatives'' and in ''weedy or invasive species.'' However, the Agency notes that the term has a different meaning in each context. When discussing a ''wild or weedy relative,'' EPA considers weedy plants to be those with the characteristics of weeds, i.e., those that are considered undesirable, unattractive, or troublesome, especially when growing where they are not wanted. However, when discussing ''weedy or invasive species,'' EPA considers a weedy species to be a species that is an aggressive competitor in natural ecosystems. EPA recognizes that it would be better to have a single definition of the term ''weedy,'' but the Agency believes both meanings of the term ''weedy'' are in common, scientific usage. In addition, the Agency is not aware of a term other than ''wild or weedy relative'' that would encompass all plants that grow outside of agricultural fields, or a term other than ''weedy or invasive species'' that would encompass all of the plants that are problematic from a management perspective. EPA would be particularly interested in alternative suggestions to describe each of these situations and thus enable the Agency to avoid using two different meanings for the word ''weedy.''

5. EPA requests comment on whether the viral interactions criterion in § 174.27(b)(1)(i) could be expanded to read ''the viral pathotype used to create the PVCP-PIP has naturally infected plants in the United States *or other parts of North America* and naturally infects plants of the same species as those containing the PVCP-PIP.'' EPA recognizes that viruses are likely to move freely across political boundaries. Thus, limiting this criterion to viruses that have naturally infected plants ''in the United States or other parts of North America'' may be most appropriate limitation for avoiding the introduction of sequences from an exotic virus into the United States through creation of a PVCP-PIP.

6. EPA requests comment on whether it is necessary for the Agency to address viral interactions, i.e., recombination, as articulated in § 174.27(b), in order for the Agency to conclude that a PVCP-PIP is low risk. EPA requests commenters to indicate whether their comments apply to RNA viruses, DNA viruses, or both. The Agency notes that a large number of PVCP-PIPs are likely to meet § 174.27(b) as proposed. EPA therefore requests commenters who believe § 174.27(b) is unnecessary to focus their remarks on why those PVCP-PIPs *that do not meet the conditions of proposed § 174.27(b)* would pose low risk with respect to recombination rather than addressing the average risk associated with PVCP-PIPs as a whole.

For the PVCP-PIPs that would only qualify for an exemption without the limitations provided by § 174.27(b), EPA does not believe the Agency can conclude low risk with respect to recombination (as the Agency must do in order to remove § 174.27(b) entirely) because the 2004 and 2005 SAPs have identified specific instances where this general conclusion may not hold. Nevertheless, EPA is considering removing this criterion in whole or in part if the Agency receives information suggesting that such factors as articulated and as incorporated into § 174.27(b) are unnecessary for concluding a particular PVCP-PIP is low risk. For example, the Agency notes that the current global movement of goods and people likely results in the at least occasional transport of plant viruses great distances from their original geographic distribution in spite of governmental efforts to limit their movement. In such a context, the Agency questions the relevance of requiring as a condition of exemption that the viral pathotype used to create the PVCP-PIP has naturally infected plants in the United States.

7. EPA requests comment on whether the protein production criterion in § 174.27(c)(1)(i) could be modified to encompass other types of PVCP-PIP constructs that mediate resistance based on PTGS. According to today's proposal, any such constructs other than those inserted only in an inverted repeat orientation or lacking a start codon would be reviewed by the Agency for lack of protein production under § 174.27(c)(2). However, if the Agency could identify additional types of constructs that would present reasonable assurance that no protein would be produced in any plant tissues at any point in the plant's developmental cycle, including if PTGS were to be suppressed, such constructs could be included under § 174.27(c)(1)(i) and would not require Agency review to verify that no protein would be produced.

8. EPA requests comment on whether the Agency could extend the proposed exemption (including regulatory text and rationale as written) to other PIPs that are based on any plant virus gene that confers virus resistance when no protein is produced from the inserted virus sequence because it is inserted only in an inverted repeat orientation and/or it lacks an initiation codon for protein synthesis. The 2005 SAP noted that ''[o]ther PIPs conferring virus resistance should be evaluated similarly as are the PVCP-PIPs, if the PIPs mode of action is via PTGS'' (Ref. 11). However, the Panel also mentioned several risk concerns associated with specific virus proteins. The Agency therefore concluded that PTGS was a necessary but not sufficient condition for expanding the exemption to other types of virus gene-based PIPs given that protein can be produced under certain circumstances from many constructs

that employ PTGS, and the Agency does not currently have sufficient information to conclude that such protein would pose low risk to the environment. In the case of the two types of inserts described above, the 2005 SAP indicated that it could be ''safely determined'' that no protein would ever be produced from such constructs (Ref. 11), and they would meet § 174.27(b) and (c). Section 174.27(a) would be evaluated as it is evaluated for PVCP-PIPs given that the relevant consideration would be the virus-resistant phenotype of the plant rather than the means by which the trait is conferred. EPA thus believes that the criteria in today's proposed exemption address all relevant risk considerations for PIPs based on any plant virus gene when no protein is produced from the inserted virus sequence. EPA is therefore inclined to expand the exemption to include PIPs based on any viral gene that confers virus resistance if the PIP meets § 174.27(a) and no protein is produced from the inserted virus sequence because it is inserted only in an inverted repeat orientation and/or it lacks an initiation codon for protein synthesis.

9. EPA requests comment on the alternative approach the Agency is considering for exempting marker genes that are used as inert ingredients with PIPs under which NPTII, GUS, and PMI would be exempt from FIFRA when used as inert ingredients with any exempt PIP, regardless of the plant in which they are expressed (as discussed in Unit IV).

10. EPA requests comment on the possibility of developing an Agency-determined approach for exempting inert ingredients under FIFRA. Under this approach, EPA would propose new language at 40 CFR 174.21(c) that would enable the Agency to review inert ingredients on a case-by-case basis to determine whether they meet the standard established for inert ingredients in 40 CFR part 174 subpart X-List of Approved Inert Ingredients. EPA is considering such a procedure to ensure that a low-risk PVCP-PIP that otherwise meets the conditions for exemption at § 174.21 would not require a FIFRA registration solely due to the presence of an inert ingredient that may prove to be low risk upon review. The only alternative to registration for such a PVCP-PIP would be to add the inert ingredient to the list through rulemaking under FIFRA section 25(b), such that the PVCP-PIP could be exempted. Rulemaking would take considerably longer than an Agency determination procedure like that described in today's proposal for other exemption criteria.

The criteria that EPA is considering for determining whether an inert ingredient would be exempt under an Agency determination are:

i. The inert ingredient is non-toxic to humans and animals and does not produce a toxic substance,

ii. The inert ingredient is non-allergenic, and

iii. If the inert ingredient is an antibiotic resistance gene or marker protein, therapy with antibiotics would not be compromised even if the gene were to be transferred from plants to microorganisms in the gut of man or animal, or in the environment.

11. EPA requests comment on the Agency's assumption in the economic analysis for this proposed rule that the estimated number of PVCP-PIPs submitted for regulatory review will be the same per year over the next 10 years. EPA assumed a uniform distribution given that the Agency lacks reliable information on which to base a more complex distribution pattern. EPA is particularly interested in any data or information supporting a different assumption for the economic analysis.

12. EPA requests comment on the usefulness of a guidance document that would provide a simplified description of the final rule. EPA intends to develop such a document and is interested to know what specific content the public would find most helpful.

VIII. References

The following books, articles, and reports were used in preparing this proposed rule and are cited in this document by the number indicated.

1. Callaway, A., Giesman–Cookmeyer, D., Gillock, E.T., Sit, T.L., Lommel, S.A. The multifunctional capsid proteins of plant RNA viruses. *Annual Review of Phytopathology* 2001; 39:419–60.

2. Kaniewski, W.K., Lawson, C. Coat protein and replicase–mediated resistance to plant viruses. In: Hadidi, A., Khetarpal, R.K., Koganezawa, H. Plant Virus Disease Control. St. Paul, Minnesota: APS Press, 1998:65–78.

3. Powell, P.A., Sanders, P.R., Tumer, N., Fraley, R.T., Beachy, R.N. Protection against tobacco mosaic virus infection in transgenic plants requires accumulation of coat protein rather than coat protein RNA sequences. *Virology* 1990; 175:124–30.

4. Goldbach, R., Bucher, E., Prins, M. Resistance mechanisms to plant viruses: an overview. *Virus Research* 2003; 92:207–12.

5. Savenkov, E.I., Valkonen, J.P.T. Silencing of a viral RNA silencing suppressor in transgenic plants. *Journal of General Virology* 2002; 83:2325–35.

6. Waterhouse, P.M., Wang, M.B., Lough, T. Gene silencing as an adaptive defence against viruses. *Nature* 2001; 411:834–42.

7. Kooter, J.M., Matzke, M.A., Meyer, P. Listening to the silent genes: transgene silencing, gene regulation and pathogen control. *Trends in Plant Science* 1999; 4:340–7.

8. Hamilton, A.J., Baulcombe, D.C. A species of small antisense RNA in posttranscriptional gene silencing in plants. *Science* 1999; 286:950–2.

9. Lu, R., Martin–Hernandez, A.M., Peart, J.R., Malcuit, I., Baulcombe, D. Virus–induced gene silencing in plants. *Methods* 2003; 30:296–303.

10. National Research Council. Genetically Modified Pest–Protected Plants: Science and Regulation. Washington, DC: National Academy Press, 2000.

11. FIFRA Scientific Advisory Panel. Minutes of the December 6–8, 2005 Meeting on Plant–Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule. 2005.

12. Bartsch, D., Schmidt, M., Pohl–Orf, M., Haag, C., Schuphan, I. Competitiveness of transgenic sugar beet resistant to beet necrotic yellow vein virus and potential impact on wild beet populations. *Molecular Ecology* 1996; 5:199.

13. National Research Council. Field Testing Genetically Modified Organisms. Washington, DC: National Academy Press, 1989.

14. Keeler, K.H. Can genetically engineered crops become weeds? *Bio/Technology* 1989; 7:1134–9.

15. National Research Council. Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation. Washington, DC: National Academy Press, 2002.

16. Wennstrom, A. Risk assessment of genetically modified undomesticated plants. In: den Nijs, H.C.M., Bartsch, D., Sweet, J. Introgression from Genetically Modified Plants. Cambridge, MA: CABI Publishing, 2004:297–307.

17. Levin, D.A. The origin of isolating mechanisms in flowering plants. *Evolutionary Biology* 1978; 11:185–317.

18. Ellstrand, N.C., Prentice, H.C., Hancock, J.F. Gene flow and introgression from domesticated plants into their wild relatives. *Annual Review of Ecology and Systematics* 1999; 30:539–63.

19. Ellstrand, N. Dangerous Liaisons. Baltimore: Johns Hopkins University Press, 2003.

20. Khetarpal, R.K., Maisonneuve, B., Maury, Y., Chalhoub, B., Dinant, S.,

Lecoq, H. et al. Breeding for resistance to plant viruses. In: Hadidi, A., Khetarpal, R.K., Koganezawa, H. Plant Virus Disease Control. St. Paul: APS Press, 1998:14–32.

21. MacClement, W.D., Richards, M.G. Virus in wild plants. *Canadian Journal of Botany* 1956; 34:793–9.

22. Barnett, O.W., Gibson, P.B. Identification and prevalence of white clover viruses and the resistance of Trifolium species to these viruses. *Crop Science* 1975; 15:32–7.

23. Hammond, J. Viruses occurring in Plantago species in England. *Plant Pathology* 1981; 30:237–44.

24. Raybould, A.F., Maskell, L.C., Edwards, M.L., Cooper, J.I., Gray, A.J. The prevalence and spatial distribution of viruses in natural populations of *Brassica oleracea. New Phytologist* 1999; 141:265.

25. FIFRA Scientific Advisory Panel. Minutes of the October 13–15, 2004 Meeting on Issues Associated with Deployment of a Type of Plant–Incorporated Protectant (PIP), Specifically those Based on Plant Viral Coat Proteins (PVCP-PIPs). 2004.

26. Duffus, J.E. Role of weeds in the incidence of virus diseases. *Annual Review of Phytopathology* 1971; 9:319–40.

27. Yahara, T., Oyama, K. Effects of virus infection on demographic traits of an agamospermous population of *Eupatorium chinense* (Asteraceae). *Oecologia* 1993; 96:310–5.

28. Funayama, S., Hikosaka, K., Yahara, T. Effects of virus infection and growth irradiance on fitness components and photosynthetic properties of *Eupatorium makinoi* (Compositae). *American Journal of Botany* 1997; 84:823–30.

29. Friess, N., Maillet, J. Influence of cucumber mosaic virus infection on the intraspecific competitive ability and fitness of purslane (*Portulaca oleracea*). New Phytologist 1996; 132:103–11.

30. Maskell, L.C., Raybould, A.F., Cooper, J.I., Edwards, M.L., Gray, A.J. Effects of turnip mosaic virus and turnip yellow mosaic virus on the survival, growth and reproduction of wild cabbage (*Brassica oleracea*). *Annals of Applied Biology* 1999; 135:401–7.

31. Gilbert, G.S. Evolutionary ecology of plant diseases in natural ecosystems. *Annual Review of Phytopathology* 2002; 40:13–43.

32. Fuchs, M., Chirco, E.M., McFerson, J.R., Gonsalves, D. Comparative fitness of a wild squash species and three generations of hybrids between wild x virus–resistant transgenic squash. *Environmental Biosafety Research* 2004; 3:17–28.

33. Sukopp, U., Pohl, M., Driessen, S., Bartsch, D. Feral beets—with help from the maritime wild? In: Gressel, J. Crop Ferality and Volunteerism. Boca Raton: CRC Press, 2005:45–57.

34. Jones, R.A.C., Nicholas, D.A. Impact of an insidious virus disease in the legume component on the species balance within self–regenerating annual pasture. *The Journal of Agricultural Science* 1998; 131:155–70.

35. Funayama, S., Terashima, I., Yahara, T. Effects of virus infection and light environment on population dynamics of *Eupatorium makinoi* (Asteraceae). *American Journal of Botany* 2001; 88:616–22.

36. Power, A.G. Ecological risks of transgenic virus–resistant crops. In: Letourneau, D.K., Burrows, B.E. Genetically Engineered Organisms: Assessing Environmental and Human Health Effects. Boca Raton: CRC Press, 2002:125–42.

37. Pilson, D., Prendeville, H.R. Ecological effects of transgenic crops and the escape of transgenes into wild populations. *Annual Review of Ecology and Systematics* 2004; 35:149–74.

38. Mitchell, C.E., Power, A.G. Release of invasive plants from fungal and viral pathogens. *Nature* 2003; 421:625–7.

39. Colautti, R.I., Ricciardi, A., Grigorovich, I.A., MacIsaac, H.J. Is invasion success explained by the enemy release hypothesis? *Ecology Letters* 2004; 7:721–33.

40. Remold, S.K. Unapparent virus infection and host fitness in three weedy grass species. *Journal of Ecology* 2002; 90:967.

41. Gibbs, A. A plant virus that partially protects its wild legume host against herbivores. *Intervirology* 1980; 13:42–7.

42. U.S. Environmental Protection Agency. Compilation of Expert Consultations on Weediness Concerns Associated with Plants that may Contain a PVCP–PIP; docket control number EPA–HQ–OPP–2006–0642. 2006.

43. Ritala, A., Nuutila, A.M., Aikasalo, R., Kauppinen, V., Tammisola, J. Measuring gene flow in the cultivation of transgenic barley. *Crop Science* 2002; 42:278–85.

44. U.S. Environmental Protection Agency. Biopesticides Registration Action Document (BRAD) - Bacillus thuringiensis Plant-Incorporated Protectants. *http://www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm.* 2001.

45. OECD Environment Directorate. Consensus document on the biology of *Zea mays* subsp. *mays* (maize). *http://www.olis.oecd.org/olis/2003doc.nsf/43bb6130e5e86e5fc12569fa005d004c/f70b80eb7cd25728c1256d57003e5f0c/$FILE/JT00147699.PDF.* 2003.

46. United States Department of Agriculture Animal and Plant Health Inspection Service. USDA-APHIS Response to Cornell University and the University of Hawaii Petition 96–051–01p for a Determination of Nonregulated Status for 'Sunset' Papaya Lines 55–1 and 63–1.

47. Chan, Y.K., Coppens d'Eeckenbrugge, G., Sanewski, G.M. Breeding and variety improvement. In: Bartholomew, D.P., Paull, R.E., Rohrbach, K.G. The Pineapple: Botany, Cultivation and Utilization. Oxon, UK: CABI Publishing, 2003:33–55.

48. OECD Environment Directorate. Consensus document on the biology of *Solanum tuberosum* subsp. *tuberosum* (potato). *http://www.oecd.org/dataoecd/25/62/27854542.pdf.* 1997.

49. United States Department of Agriculture Animal and Plant Health Inspection Service. USDA/APHIS Petition 94–257 for Determination of Nonregulated Status for Colorado Potato Beetle-Resistant Potato Lines BT6, BT10, BT12, BT16, BT17, BT18, and BT23. 1995.

50. OECD Environment Directorate. Consensus document on the biology of *Glycine max* (L.) Merr. (soybean). *http://www.olis.oecd.org/olis/2000doc.nsf/4f7adc214b91a685c12569fa005d0ee7/c125692700623b74c1256996003e87fc/$FILE/00085953.PDF.* 2000.

51. Haygood, R., Ives, A.R., Andow, D.A. Population genetics of transgene containment. *Ecology Letters* 2004; 7:213–20.

52. Barton, N.H. The effects of linkage and density-dependent regulation on gene flow. *Heredity* 1986; 57:415–26.

53. National Research Council. Biological Confinement of Genetically Engineered Organisms. Washington, DC: National Academies Press, 2004.

54. Al-Ahmad, H., Galili, S., Gressel, J. Poor competitive fitness of transgenically mitigated tobacco in competition with the wild type in a replacement series. *Planta* 2005; 222:372–85.

55. Gressel, J., Al-Ahmad, H. Assessing and managing biological risks of plants used for bioremediation, including risks of transgene flow. *Zeitschrift für Naturforschung.C, A journal of biosciences* 2005; 60:154–65.

56. Hull, R. Matthews' Plant Virology, Fourth ed. San Diego: Academic Press, 2002.

57. Hammond, J., Lecoq, H., Raccah, B. Epidemiological risks from mixed virus infections and transgenic plants expressing viral genes. *Advances in Virus Research* 1999; 54:189–314.

58. Falk, B.W., Bruening, G. Will transgenic crops generate new viruses and new diseases? *Science* 1994; 263:1395–6.

59. de Zoeton, G.A. Risk assessment: Do we let history repeat itself? *Phytopathology* 1991; 81:585–6.

60. U.S. Environmental Protection Agency. Viral Interactions in Viral Coat Protein Transgenic Plants: A Literature Review. 2004. Washington, DC, Office of Science Coordination and Policy, Office for Prevention, Pesticides and Toxic Substances.

61. Fraile, A., Alonso-Prados, J.L., Aranda, M.A., Bernal, J.J., Malpica, J.M., García-Arenal, F. Genetic exchange by recombination or reassortment is infrequent in natural populations of a tripartite RNA plant virus. *Journal of Virology* 1997; 71:934–40.

62. Salánki, K., Carrére, I., Jacquemond, M., Balázs, E., Tepfer, M. Biological properties of pseudorecombinant and recombinant strains created with cucumber mosaic virus and tomato aspermy virus. *Journal of Virology* 1997; 71:3597–602.

63. Aaziz, R., Tepfer, M. Recombination between genomic RNAs of two cucumoviruses under conditions of minimal selection pressure. *Virology* 1999; 263:282–9.

64. Spitsin, S., Steplewski, K., Fleysh, N., Belanger, H., Mikheeva, T., Shivprasad, S. et al. Expression of alfalfa mosaic virus coat protein in tobacco mosaic virus (TMV) deficient in the production of its native coat protein supports long-distance movement of a chimeric TMV. *Proceedings of the National Academy of Sciences* 1999; 96:2549–53.

65. Allison, R.F., Janda, M., Ahlquist, P. Sequence of cowpea chlorotic mottle virus RNAs 2 and 3 and evidence of a recombination event during bromovirus evolution. *Virology* 1989; 172:321–30.

66. Gibbs, M.J., Cooper, J.I. A recombinational event in the history of luteoviruses probably induced by base-pairing between the genomes of two distinct viruses. *Virology* 1995; 206:1129–32.

67. Le Gall, O.L., Lanneau, M., Candresse, T., Dunez, J. The nucleotide sequence of the RNA-2 of an isolate of the English serotype of tomato black ring virus: RNA recombination in the history of nepoviruses. *Journal of General Virology* 2003; 76:1279–83.

68. Masuta, C., Ueda, S., Suzuki, M., Uyeda, I. Evolution of a quadripartite hybrid virus by interspecific exchange and recombination between replicase components of two related tripartite RNA viruses. *Proceedings of the National Academy of Sciences* 1998; 95:10487–92.

69. Moonan, F., Molina, J., Mirkov, T.E. Sugarcane yellow leaf virus: an emerging virus that has evolved by recombination between luteoviral and poleroviral ancestors. *Virology* 2000; 269:156–71.

70. Desbiez, C., Lecoq, H. The nucleotide sequence of Watermelon mosaic virus (WMV, Potyvirus) reveals interspecific recombination between two related potyviruses in the 5' part of the genome. *Archives of Virology* 2004; 149:1619–32.

71. Chenault, K.D., Melcher, U. Phylogenetic relationships reveal recombination among isolates of cauliflower mosaic virus. *Journal of Molecular Evolution* 1994; 39:496–505.

72. Pita, J.S., Fondong, V.N., Sangare, A., Otim-Nape, G.W., Ogwal, S., Fauquet, C.M. Recombination, pseudorecombination and synergism of geminiviruses are determinant keys to the epidemic of severe cassava mosaic disease in Uganda. *Journal of General Virology* 2001; 82:655–65.

73. Zhou, X., Liu, Y., Calvert, L., Munoz, C., Otim-Nape, G.W., Robinson, D.J. et al. Evidence that DNA-A of a geminivirus associated with severe cassava mosaic disease in Uganda has arisen by interspecific recombination. *Journal of General Virology* 1997; 78:2101–11.

74. Fauquet, C.M., Sawyer, S., Idris, A.M., Brown, J.K. Sequence analysis and classification of apparent recombinant Begomoviruses infecting tomato in the Nile and Mediterranean Basins. *Phytopathology* 2005; 95:549–55.

75. Monci, F., S´nchez-Campos, S., Navas-Castillo, J., Moriones, E. A natural recombinant between the Geminiviruses Tomato yellow leaf curl Sardinia virus and Tomato yellow leaf curl virus exhibits a novel pathogenic phenotype and is becoming prevalent in Spanish populations. *Virology* 2002; 303:317–26.

76. Baliji, S., Black, M.C., French, R., Stenger, D.C., Sunter, G. Spinach curly top virus: A newly described Curtovirus species from southwest Texas with incongruent gene phylogenies. *Phytopathology* 2004; 94:772–8.

77. Mayo, M.A., Jolly, C.A. The 5'-terminal sequence of potato leafroll virus RNA: evidence of recombination between virus and host RNA. *Journal of General Virology* 1991; 72:2591–5.

78. Rubio, T., Borja, M., Scholthof, H.B., Jackson, A.O. Recombination with host transgenes and effects on virus evolution: an overview and opinion. *Molecular Plant-Microbe Interactions* 1999; 12:87–92.

79. Lommel, S.A., Xiong, Z. Reconstitution of a functional red clover necrotic mosaic virus by recombinational rescue of the cell-to-cell movement gene expressed in a transgenic plant. *Journal of Cell Biochemistry* 1991; 15A:151.

80. Greene, A.E., Allison, R.F. Recombination between viral RNA and transgenic plant transcripts. *Science* 1994; 263:1423–5.

81. Borja, M., Rubio, T., Scholthof, H.B., Jackson, A.O. Restoration of wild-type virus by double recombination of tombusvirus mutants with a host transgene. *Molecular Plant-Microbe Interactions* 1999; 12:153–62.

82. Adair, T.L., Kearney, C.M. Recombination between a 3-kilobase tobacco mosaic virus transgene and a homologous viral construct in the restoration of viral and nonviral genes. *Archives of Virology* 2000; 145:1867–83.

83. Varrelmann, M., Palkovics, L., Maiss, E. Transgenic or plant expression vector-mediated recombination of Plum pox virus. *Journal of Virology* 2000; 74:7462–9.

84. Gal, S., Pisan, B., Hohn, T., Grimsley, N., Hohn, B. Agroinfection of transgenic plants leads to viable cauliflower mosaic virus by intermolecular recombination. *Virology* 1992; 187:525–33.

85. Schoelz, J.E., Wintermantel, W.M. Expansion of viral host range through complementation and recombination in transgenic plants. *Plant Cell* 1993; 5:1669–79.

86. Wintermantel, W.M., Schoelz, J.E. Isolation of recombinant viruses between cauliflower mosaic virus and a viral gene in transgenic plants under conditions of moderate selection pressure. *Virology* 1996; 223:156–64.

87. Frischmuth, T., Stanley, J. Recombination between viral DNA and the transgenic coat protein gene of African cassava mosaic geminivirus. *Journal of General Virology* 1998; 79:1265–71.

88. Falk, B.W., Passmore, B.K., Watson, M.T., Chin, L.S. The specificity and significance of heterologous encapsidation of virus and virus-like RNAs. In: Bills, D.D., Kung, S.D. Biotechnology and Plant Protection: Viral pathogenesis and disease resistance. Singapore: World Scientific, 1995:391–415.

89. Tepfer, M. Viral genes and transgenic plants: What are the potential environmental risks? *Biotechnology (N Y)* 1993; 11:1125–32.

90. Rochow, W.F. Barley yellow dwarf virus: phenotypic mixing and vector specificity. *Science* 1970; 167:875–8.

91. Creamer, R., Falk, B.W. Direct detection of transcapsidated barley yellow dwarf luteoviruses in doubly

infected plants. *Journal of General Virology* 1990; 71:211–7.

92. Bourdin, D., Lecoq, H. Evidence that heteroencapsidation between two potyviruses is involved in aphid transmission of a non-aphid-transmissible isolate from mixed infections. *Phytopathology* 1991; 81:1459–64.

93. Taliansky, M.E., Robinson, D.J. Molecular biology of umbraviruses: phantom warriors. *Journal of General Virology* 2003; 84:1951–60.

94. Osbourn, J.K., Sarkar, S., Wilson, T.M.A. Complementation of coat protein-defective TMV mutants in transgenic tobacco plants expressing TMV coat protein. *Virology* 1990; 179:921–5.

95. Candelier-Harvey, P., Hull, R. Cucumber mosaic virus genome is encapsidated in alfalfa mosaic virus coat protein expressed in transgenic tobacco plants. *Transgenic Research* 1993; 2:277–85.

96. Lecoq, H., Ravelonandro, M., Wipf-Scheibel, C., Monsion, M., Raccah, B., Dunez, J. Aphid transmission of a non-aphid-transmissible strain of zucchini yellow mosaic potyvirus from transgenic plants expressing the capsid protein of plum pox potyvirus. *Molecular Plant-Microbe Interactions* 1993; 6:403–6.

97. Maiss, E., Koenig, R., Lesemann, D.E. Heterologous encapsidation of viruses in transgenic plants and in mixed infections. In: Jones, D.D. Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. Oakland: University of California , Division of Agriculture and Natural Resources, 1994:129–39.

98. Robinson, D.J. Environmental risk assessment of releases of transgenic plants containing virus-derived inserts. *Transgenic Research* 1996; 5:359–62.

99. Robinson, D.J., Ryabov, E.V., Raj, S.K., Roberts, I.M., Taliansky, M.E. Satellite RNA is essential for encapsidation of groundnut rosette umbravirus RNA by groundnut rosette assistor luteovirus coat protein. *Virology* 1999; 254:105–14.

100. Fuchs, M., Gal-On, A., Raccah, B., Gonsalves, D. Epidemiology of an aphid nontransmissible potyvirus in fields of nontransgenic and coat protein transgenic squash. *Transgenic Research* 1999; 8:429–39.

101. Losey, J.E., Eubanks, M.D. Implications of pea aphid host-plant specialization for the potential colonization of vegetables following post-harvest emigration from forage crops. *Environmental Entomology* 2000; 29:1283–8.

102. Vance, V.B., Berger, P.H., Carrington, J.C., Hunt, A.G., Shi, X.M. 5' proximal potyviral sequences mediate potato virus X/potyviral synergistic disease in transgenic tobacco. *Virology* 1995; 206:583–90.

103. OECD Environment Directorate. Consensus document on general information concerning the biosafety of crop plants made virus resistant through coat protein gene-mediated protection. *http://www.olis.oecd.org/olis/1996doc.nsf/62f30f71be4ed8a24125669e003b5f73/ce3a104b8ada9e8ac12563e2003183bb/$FILE/11E63213.ENG*. 1996.

104. Miller, W.A., Koev, G., Mohan, B.R. Are there risks associated with transgenic resistance to luteoviruses? *Plant Disease* 1997; 81:700–10.

105. Pruss, G.J., Ge, X., Shi, X.M., Carrington, J.C., Vance, V.B. Plant viral synergism: the potyviral genome encodes a broad-range pathogenicity enhancer that transactivates replication of heterologous viruses. *The Plant Cell* 1997; 9:859–68.

106. García-Arenal, F., Malpica, J.M., Fraile, A. Evolution of plant virus populations: The role of genetic exchange. In: Fairbairn, C., Scoles, G., McHughen, A. Proceedings of the 6th International Symposium on the Biosafety of Genetically Modified Organisms. Saskatoon, Canada: University Extension Press, University of Saskatchewan, 2000:91–6.

107. Thomas, P.E., Hassan, S., Kaniewski, W.K., Lawson, E.C., Zalewski, J.C. A search for evidence of virus/transgene interactions in potatoes transformed with the potato leafroll virus replicase and coat protein genes. *Molecular Breeding* 1998; 4:407–17.

108. Fuchs, M., Klas, F.E., McFerson, J.R., Gonsalves, D. Transgenic melon and squash expressing coat protein genes of aphid-borne viruses do not assist the spread of an aphid non-transmissible strain of cucumber mosaic virus in the field. *Transgenic Research* 1998; 7:449–62.

109. Lin, H.X., Rubio, L., Smythe, A., Jiminez, M., Falk, B.W. Genetic diversity and biological variation among California isolates of Cucumber mosaic virus. *Journal of General Virology* 2003; 84:249–58.

110. Vigne, E., Komar, V., Fuchs, M. Field safety assessment of recombination in transgenic grapevines expressing the coat protein gene of Grapevine fanleaf virus. *Transgenic Research* 2004; 13:165–79.

111. Allison, R.F., Schneider, W.L., Greene, A.E. Recombination in plants expressing viral transgenes. *Seminars in Virology* 1996; 7:417–22.

112. Rovere, C.V., del Vas, M., Hopp, H.E. RNA-mediated virus resistance. *Current Opinion in Biotechnology* 2002; 13:167–72.

113. Allison, R.F., Schneider, W.L., Deng, M. Risk assessment of virus resistant transgenic plants. In: Schiemann, J. The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. Berlin: Biologische Bundesanstalt für Land- und Forstwirtschaft, 2000:186–8.

114. Dinant, S., Blaise, F., Kusiak, C., Astier-Manifacier, S., Albouy, J. Heterologous resistance to potato virus Y in transgenic tobacco plants expressing the coat protein gene of lettuce mosaic potyvirus. *Phytopathology* 1993; 83:819–24.

115. Teycheney, P.Y., Aaziz, R., Dinant, S., Salánki, K., Tourneur, C., Balázs, E. et al. Synthesis of (-)-strand RNA from the 3' untranslated region of plant viral genomes expressed in transgenic plants upon infection with related viruses. *Journal of General Virology* 2000; 81:1121–6.

116. AIBS. Transgenic virus-resistant plants and new plant viruses. *http://www.aphis.usda.gov/ppq/biotech/virus/95_virusrept.pdf*. 1995.

117. Greene, A.E., Allison, R.F. Deletions in the 3' untranslated region of cowpea chlorotic mottle virus transgene reduce recovery of recombinant viruses in transgenic plants. *Virology* 1996; 225:231–4.

118. Nagy, P.D., Ogiela, C., Bujarski, J.J. Mapping sequences active in homologous RNA recombination in brome mosaic virus: prediction of recombination hot spots. *Virology* 1999; 254:92–104.

119. Miller, W.A., Koev, G., Beckett, R. Issues surrounding transgenic resistance to the *Luteoviridae*. In: Schiemann, J. The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. Berlin: Biologische Bundesanstalt für Land- und Forstwirtschaft, 2000:203–9.

120. Nagy, P.D., Zhang, C., Simon, A.E. Dissecting RNA recombination in vitro: role of RNA sequences and the viral replicase. *The EMBO Journal* 1998; 17:2392–403.

121. Gibbs, M. Risks in using transgenic plants? *Science* 1994; 264:1650–1.

122. Hull, R. Risks in using transgenic plants? *Science* 1994; 264:1649–50.

123. U.S. Environmental Protection Agency. Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn (006484) Biopesticide Registration Action Document (BRAD). *http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/brad_006484.htm*. 2003.

124. U.S. Environmental Protection Agency. Biopesticides Registration Action Document (BRAD)—*Bacillus thuringiensis* Cry2Ab2 protein and its genetic material necessary for its production in cotton. *http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/brad_006487.pdf*. 2002.

125. Gonsalves, D., Manshardt, R. Petition 96–051–01p for Determination of Regulatory Status: Transgenic Papaya lines 55–1 and their Derivatives. 1996.

126. Codex Alimentarius Commission. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. 2003.

127. Smalla, K., Borin, S., Heuer, H., Gebhard, F., van Elsas, J.D., Nielsen, K. Horizontal transfer of antibiotic resistance genes from transgenic plants to bacteria — are there new data to fuel the debate? In: Fairbairn, C., Scoles, G., McHughen, A. Proceedings of the 6th International Symposium on the Biosafety of Genetically Modified Organisms. Saskatchewan: University Extension Press, 2000:146–54.

128. Tolin, S.A. Persistence, establishment, and mitigation of phytopathogenic viruses. In: Levin, M.A., Strauss, H.S. Risk Assessment in Genetic Engineering. New York: McGraw-Hill, Inc., 1991:114–39.

129. Abbas, M., Khan, M.M., Mughal, S.M., Khan, I.A. Prospects of classical cross protection technique against *Citrus tristeza closterovirus* in Pakistan. *Horticultural Science* (Prague) 2005; 32:74–83.

130. EPPO/CABI. Quarantine Pests for Europe, 2nd ed. Wallingford, UK: CABI International, 1997.

131. International Food Biotechnology Council. Biotechnologies and food: Assuring the safety of foods produced by genetic modification. *Regulatory Toxicology and Pharmacology* 1990; 12(3).

132. Quemada, H. Food safety evaluation of a transgenic squash. OECD Workshop on Food: Provisional Proceedings of the Safety Evaluation. Paris: OECD, 1994:71–9.

133. Berg, J., Tymoczko, J., Stryer, L., Clarke, N. Biochemistry, 5th ed. New York: W. H. Freeman and Company, 2002.

134. Stewart, C.N.Jr., Halfhill, M.D., Warwick, S.I. Transgene introgression from genetically modified crops to their wild relatives. *Nature Reviews Genetics* 2003; 4:806–17.

135. Bartsch, D., Brand, U., Morak, C., Pohl-Orf, M., Schuphan, I., Ellstrand, N. Biosafety of hybrids between transgenic virus-resistant sugar beet and swiss chard. *Ecological Applications* 2001; 11:142–7.

136. Spencer, L.J., Snow, A.A. Fecundity of transgenic wild-crop hybrids of *Cucurbita pepo* (Cucurbitaceae): implications for crop-to-wild gene flow. *Heredity* 2001; 86:694–702.

137. Ilardi, V., Barba, M. Assessment of functional transgene flow in tomato fields. *Molecular Breeding* 2001; 8:311–5.

138. Fuchs, M., Chirco, E.M., Gonsalves, D. Movement of coat protein genes from a commercial virus-resistant transgenic squash into a wild relative. *Environmental Biosafety Research* 2004; 3:5–16.

139. Bartsch, D. Ecological impact of transgenic virus-resistance in crop, weed, and wild plant populations (due to potential alterations of plant invasiveness). In: Tepfer, M., Balázs, E. Virus-resistant Transgenic Plants: Potential Ecological Impact. Berlin: Springer, 1997:107–13.

140. Tepfer, M. Risk assessment of virus-resistant transgenic plants. *Annual Review of Phytopathology* 2002; 40:467–91.

IX. Content of Official Record

EPA has established an official record for this rulemaking. The official record includes all information considered by EPA in developing this proposed rule including documents specifically referenced in this action, any public comments received during an applicable comment period, and any other information related to this action, including any information claimed as CBI and any information received in any of the related dockets mentioned below. This official record includes all information physically located in the dockets described in the following paragraph, as well as any documents that are referenced in the documents in the dockets. The public version of the official record does not include any information claimed as CBI.

The complete official record for this rulemaking includes:

The docket identified by the docket control number OPP–300370 for the document entitled ''Proposed Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act'' (59 FR 60496, November 23, 1994)(FRL–4755–2).

The docket identified by the docket control number OPP–300369 for the document entitled ''Plant-Pesticides Subject to the Federal Insecticide, Fungicide and Rodenticide Act; Proposed Rule'' (59 FR 60519, November 23, 1994)(FRL–4755–3).

The docket identified by the docket control number OPP–300368 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act'' (59 FR 60535, November 23, 1994)(FRL–4758–8).

The docket identified by the docket control number OPP–300371 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants'' (59 FR 60542, November 23, 1994)(FRL–4755–5).

The docket identified by the docket control number OPP–300367 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants'' (59 FR 60545, November 23, 1994)(FRL–4755–4).

The docket identified by the docket control number OPP–300370A for the document entitled ''Plant-Pesticide Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Reopening of Comment Period'' (61 FR 37891, July 22, 1996)(FRL–5387–4).

The docket identified by the docket control number OPP–300368A for the document entitled ''Plant-Pesticides; Supplemental Notice of Proposed Rulemaking'' (62 FR 27132, May 16, 1997)(FRL–5717–2).

The docket identified by the docket control number OPP–300371A for the document entitled ''Plant-Pesticides; Nucleic Acids; Supplemental Notice of Proposed Rulemaking'' (62 FR 27142, May 16, 1997)(FRL–5716–7).

The docket identified by the docket control number OPP–300367A for the document entitled ''Plant-Pesticides; Viral Coat Proteins; Supplemental Notice of Proposed Rulemaking'' (62 FR 27149, May 16, 1997)(FRL–5716–6).

The docket identified by the docket control number OPP–300369A for the document entitled ''Plant-Pesticides, Supplemental Notice of Availability of Information'' (64 FR 19958, April 23, 1999)(FRL–6077–6).

The docket identified by the docket control number OPP–300369B for the document entitled ''Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37772, July 19, 2001)(FRL–6057–7).

The docket identified by the docket control number OPP–300368 for the document entitled ''Exemption From

the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived through Conventional Breeding From Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37830, July 19, 2001)(FRL–6057–6).

The docket identified by the docket control number OPP–300371 for the document entitled ''Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37817, July 19, 2001)(FRL–6057–5).

The docket identified by the docket control number OPP–300370B for the document entitled ''Plant-Incorporated Protectants (Formerly Plant-Pesticides), Supplemental Proposal'' (66 FR 37855, July 19, 2001)(FRL–6760–4).

The docket identified by the docket control number EPA–HQ–OPP–2006–0643 for the companion document entitled ''Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues of Plant Virus Coat Proteins that are Part of a Plant-Incorporated Protectant (PVC-Proteins)'' (FRL–8100–5) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number EPA–HQ–OPP–2006–0642 for this document (FRL–8100–7).

Also included in the complete official record are:

1. Public comments submitted in response to the proposals and supplemental documents cited in the above paragraph.
2. Reports of all meetings of the Biotechnology Science Advisory Committee and the FIFRA Scientific Advisory Panel pertaining to the development of this proposed rule.
3. The Economic Analysis for this proposed rule and supporting documents.
4. Support documents and reports.
5. Records of all communications between EPA personnel and persons outside EPA pertaining to the proposed rule. (This does not include any inter- and intra-agency memoranda, unless specifically noted in the indices of the dockets).
6. Published literature that is cited in this document.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

Pursuant to Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this is a ''significant regulatory action'' because it may raise potentially novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Therefore, this action was submitted to OMBfor review, and changes made during that review have been documented in the docket.

In addition, EPA has prepared an economic analysis of the impacts related to this proposed action. The economic analysis evaluates the quantifiablebenefits of exempting PVCP-PIPs from FIFRA requirements (40 CFR part174) and discusses the non-quantifiable benefits of this action. Thiseconomic analysis is contained in a document entitled ''EconomicAnalysis for Proposed Exemption Under the Federal Insecticide,Fungicide, and Rodenticide Act for Certain Plant-IncorporatedProtectants Derived from a Plant Viral Coat Protein Gene (PVCP-PIPs)''(called here ''the EA''). This document is available in thedocket and is briefly summarized in Unit V.

B. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501et seq., an Agency may not conduct or sponsor, and a person is notrequired to respond to a collection of information unless it displays acurrently valid OMB control number, or is otherwise required to submitthe specific information by a statute. The OMB control numbers for EPA's regulations codified in Title 40 of the CFR, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in a list at 40 CFR 9.1.

The information collection requirements contained in thisproposed rule have been submitted to OMB for review and approvalunder the PRA in accordance with the procedures at 5 CFR 1320.11.The burden and costs related to the information collection requirementscontained in this rule are described in an addendum to a currently approved Information Collection Request (ICR) identified as EPA ICR No. 1693.04 (OMB number 2070–0142). As defined in the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes ofcollecting, validating, and verifying information, processing andmaintaining information, and disclosing and providing information;adjust the existing ways to comply with any previously applicableinstructions and requirements; train personnel to be able to respond toa collection of information; search data sources; complete and reviewthe collection of information; and transmit or otherwise disclose theinformation.

This proposed rule includes information collection requirements ofdevelopers who wish to exempt PVCP-PIPs under the provisions of theproposed rule. Developers self-determining their exemption status willhave to develop and maintain records supporting their determinationand report their determination to EPA. Developers relying on Agencydetermination of exemption status will have to develop the informationneeded for the Agency determination and submit it to EPA. The Agencyhas estimated that this information collection has an estimated burdenof 21.5 hours per response for developer-determined exemptions and23.5 hours per response for Agency-determined exemptions. EPAestimates that there will be one submission of each type per year fora total annual respondent burden of 45 hours.

Direct your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to EPA using the public docket that has been established for this proposed rule (Docket ID No. EPA–HQ–OPP–2006–0642). In addition, send a copy of your comments about the ICR to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, Attention: Desk Office for EPA ICR No. 2070–0142. Since OMB is required to complete its review of the ICR between 30 and 60 days after April 18, 2007, please submit your ICR comments for OMB consideration to OMB by May 18, 2007.

The Agency will consider and address comments received on theinformation collection requirements contained in this proposal whenit develops the final rule.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 USC 601 et seq., the Agency hereby certifies

that this rule will not have a significant adverse economic impact on a substantial number of small entities.

For purposes of assessing the impacts of today's rule on smallentities, small entity is defined as: (1) a small business according tothe small business size standards established by the U.S. Small BusinessAdministration (SBA), which in this case is a pesticides and agriculturalchemical producer (NAICS code 325320) with fewer than 500employees; a crop producer (NAICS code 111) with less than $750,000in revenues; a college, university, or professional school (NAICS code611310) with annual revenues less than $6.5 million; or an entity inresearch and development in the physical, engineering, and lifesciences (NAICS code 54171) with fewer than 500 employees; (2) asmall governmental jurisdiction that is a government of a city, county,town, school district or special district with a population of less than50,000; and (3) a small organization that is any not-for-profit enterprisewhich is independently owned and operated and is not dominant inits field.

In determining whether a rule has a significant economic impacton a substantial number of small entities, the impact of concern is anysignificant adverse economic impact on small entities, since the primarypurpose of the regulatory flexibility analyses is to identify and addressregulatory alternatives ''which minimize any significant economicimpact of the proposed rule on small entities'' (5 U.S.C. 603 and 604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden or otherwise has a positive economic effect on all of the small entities subject to the rule. This proposed rule will generate savings by exempting PVCP-PIPs with a low probability of risk from FIFRA requirements. Given the overall potential savings attributed to this rule, the Agency concludes that this proposed action will not result in adverse economic impacts, regardless of the size of the firm currently developing and testing PVCP-PIPs or planning to develop and test PVCP-PIPs. Today's action relieves a regulatory burden. Nevertheless, the Agency continues to be interestedin the potential impacts of the proposed rule on small entities andwelcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA),Public Law 104–4, EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more forState, local or tribal governments, in the aggregate, or on the privatesector in any one year. The analysis of the cost savings associated withthis action are described in Unit V of this preamble. The requirementsof sections 202, 203, 204 or 205 of UMRA which relate to regulatoryrequirements that might significantly or uniquely affect smallgovernments and to regulatory proposals that contain a significantFederal intergovernmental mandate, respectively, do not apply totoday's rule because the rule affects only the private sector, i.e., personsfield testing such as universities, multinational companies,biotechnology companies, chemical companies, seed companies;persons selling and distributing such as multinational companies,biotechnology companies, chemical companies, seed companies; andpersons using PVCP-PIPs such as farmers.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) EPA has determined that this proposed rule does not have federalism implications, because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The primary result of this action is to exempt certain PVCP-PIPs from most FIFRA requirements. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175

Pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), EPA has concluded that this rule does not have tribal implications because it will not have any affect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Executive Order. EPA is proposing to exempt certain PVCP-PIPs from most FIFRA requirements. This is only expected to affect the private sector, not tribes or tribal governments. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866, nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

H. Executive Order 13045

This rule is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because because it is not designated as an ''economically significant'' regulatory action as defined in Executive Order 12866 and because the Agency does not have reason to believe that the environmental health or safety risks addressed by this action presentdisproportionate risks to children. The Agency has determined that thePVCP-PIPs that would be exempted by this rule pose only a lowprobability of risk to human health, including the health of infants andchildren, and that there is a reasonable certainty no harm will resultto infants and children from aggregate exposure to residues of thesePVCP-PIPs in food. Existing information suggests there are nodisproportionate effects on infants or children from dietary or otherexposures. EPA's assessment and the results of its assessment arecontained in Unit VIII of the companion document publishedelsewhere in this issue of the **Federal Register** exempting from the FFDCA section 408 requirement of a tolerance, residues of the plantvirus coat protein portion of a PVCP-PIP.

I. National Technology Transfer Advancement Act

This rule does not involve a regulatory action that would requirethe Agency to consider voluntary consensus standards pursuant tosection 12(d) of the National Technology Transfer and AdvancementAct of 1995 (NTTAA), (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntaryconsensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus

standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards when the NTTAA directs the Agency to do so.

J. Executive Order 12898

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-IncomePopulations* (59 FR 7629, February 16, 1994), EPA has consideredenvironmental justice related issues with regard to the potential impactsof this action on the environmental and health conditions in low incomeand minority communities. The Agency is required to considerthe potential for differential impacts on sensitive sub-populations. EPAconsidered available information on the sensitivities of subgroups aspertains to the exemptions. EPA concluded that no subgroup would bedifferentially affected. See also the companion document ''Exemptionfrom the Requirement of a Tolerance under the Federal Food, Drug, andCosmetic Act for Residues of Plant Virus Coat Proteins that are Partof a Plant-Incorporated Protectant (PVC-Proteins)'' published elsewherein this issue of the **Federal Register**.

XI. FIFRA Review Requirements

In accordance with FIFRA section 25(d), EPA submitted a draft of thisproposed rule to the FIFRA Scientific Advisory Panel, the Secretary of Agriculture, and to the Committee of Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedures, Pesticides and pests.

Dated: April 9, 2007.

Stephen L. Johnson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 174—[AMENDED]

1. The authority citation for part 174 would continue to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

2. By alphabetically adding to § 174.3 new definitions to read as follows:

§ 174.3 Definitions.

* * * * *

Naturally infect means to infect by transmission to a plant through direct plant-to-plant contact (e.g., pollen or seed), an inanimate object (e.g., farm machinery), or vector (e.g., arthropod, nematode, or fungus). It does not include infection by transmission that occurs only through intentional human intervention, e.g., manual infection in a laboratory or greenhouse setting.

* * * * *

PVCP-PIP is a plant-incorporated protectant derived from one or more genes that encode a coat protein of a virus that naturally infects plants. This includes plant-incorporated protectants derived from one or more plant viral coat protein genes that produce only RNA and no virus-related protein.

PVC-protein is the plant virus coat protein portion of a PVCP-PIP.

* * * * *

United States means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the PacificIslands, and American Samoa.

Unmodified means having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus.

* * * * *

Virtually unmodified means having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus, except for the addition of one or two amino acids at the N- and/or C-terminus other than cysteine, asparagines, serine, and threonine and/or the deletion of one or two amino acids at the N- and/or C-terminus.

Weedy species means a species that is an aggressive competitor in natural ecosystems.

* * * * *

3. In § 174.21 by revising the introductory text and paragraph (c) to read as follows:

§ 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of § 174.71, if it meets all of the following criteria. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

* * * * *

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at §§ 174.485 through 174.486.

4. By adding § 174.27 to subpart B to read as follows:

§ 174.27 Plant-incorporated protectant derived from a coat protein gene(s) from a virus(es) that naturally infects plants (PVCP-PIP).

In order for a plant-incorporated protectant derived from one or more genes that encode a coat protein of a virus that naturally infects plants (PVCP-PIP) to be exempt, the criteria in paragraphs (a), (b), and (c) and the requirements in paragraph (d) of this section must all be satisfied.

(a) The criterion in paragraph (a) of this section is satisfied if either paragraph (a)(1) or paragraph (a)(2) of this section applies:

(1) The plant containing the PIP is one of the following: anthurium (*Anthurium* spp.), asparagus (*Asparagus officinale*), avocado (*Persea americana*), banana (*Musa acuminata*), barley (*Hordeum vulgare*), bean (*Phaseolus vulgaris*), cacao (*Theobroma cacao*), carnation (*Dianthus caryophyllus*), chickpea (*Cicer arietinum*), citrus (*Citrus* spp., e.g., *Citrus aurantifolia*, *Citrus limon*, *Citrus paradisii*, *Citrus sinensis*), coffee (*Coffea arabica* and *Coffea canephora*), corn (*Zea maize*), cowpea (*Vigna unguiculata*), cucumber (*Cucumis sativus*), gerbera (*Gerbera* spp.), gladiolus (*Gladiolus* spp.), lentil (*Lens culinaris*), mango (*Mangifera indica*), orchids (*Orchidaceae*), papaya (*Carica papaya*), pea (*Pisum sativum*), peanut (*Arachis hypogaea*), pineapple (*Ananas comosus*), potato (*Solanum tuberosum*), soybean (*Glycine max*), starfruit (*Averrhoa carambola*), sugarcane (*Saccharum officinarum*), or tulips (*Tulipa* spp.).

(2) The Agency determines after review that the plant containing the PIP meets paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this section:

(i) Has no wild or weedy relatives in the United States with which it can form viable hybrids in nature.

(ii) Is not a weedy or invasive species outside of agricultural fields in the United States.

(iii) Is unlikely to establish weedy or invasive populations outside of agricultural fields in the United States even if the plant contains a PVCP-PIP.

(b) The criterion in paragraph (b) of this section is satisfied if either paragraph (b)(1)(i), paragraph (b)(1)(ii), or paragraph (b)(2) of this section applies:

(1)(i) The viral pathotype used to create the PVCP-PIP has naturally infected plants in the United States and naturally infects plants of the same species as those containing the PVCP-PIP, or

(ii) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is

inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant.

(2) The Agency determines after review that viruses that naturally infect the plant containing the PVCP-PIP are unlikely to acquire the coat protein sequence through recombination and produce a viable virus with significantly different properties than either parent virus.

(c) The criterion in paragraph (c) of this section is satisfied if either paragraph (c)(1) or paragraph (c)(2) of this section applies:

(1) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance:

(i) Is inserted only in an inverted repeat orientation or lacking an initiation codon for protein synthesis such that no PVC-protein is produced in the plant, or

(ii) Encodes only a single virtually unmodified viral coat protein. Multiple PVC-proteins could each separately meet this criterion. Chimeric PVC-proteins do not qualify.

(2) The Agency determines after review that the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance:

(i) Encodes a protein that is minimally modified from a coat protein from a virus that naturally infects plants, or

(ii) Produces no protein.

(d)(1) Records to support exemption determinations made by the developer of a PVCP-PIP under paragraphs (a)(1), (b)(1), or (c)(1) of this section; to support a submission of information under paragraphs (a)(2), (b)(2), or (c)(2) of this section; or to support a certification made by the developer that a PVCP-PIP meets § 174.21(b) and/or § 174.21(c) must be maintained by the developer of the product for the duration of time that the PVCP-PIP is sold or distributed. Such records must be made available for inspection and copying, or otherwise submitted to the Agency for review upon request by EPA or its duly authorized representative.

(2) Information adequate to support claims for an Agency-determined exemption must be submitted for review to the Office of Pesticide Programs, Attention: PVCP-PIP Exemption.

(3) A statement notifying the Agency and certifying the accuracy of any determination made by the developer that a PVCP-PIP meets § 174.21(b), § 174.21(c), paragraph (a)(1) of this section, paragraph (b)(1) of this section, and/or paragraph (c)(1) of this section must be signed by the developer and submitted to the Office of Pesticide Programs, Attention: PVCP-PIP Exemption. Any such statement must be submitted at the time of a first submission, if any, of information under paragraph (d)(2) of this section for a particular PVCP-PIP. If a PVCP-PIP satisfies paragraphs (a)(1), (b)(1), and (c)(1)) of this section and §§ 174.21(b) and (c), the developer must submit a notification to the Agency of that determination and certify that the PVCP-PIP qualifies for exemption under FIFRA, i.e., that the PVCP-PIP meets §§ 174.21(a), (b), and (c).This certification must contain:

(i) The name of the crop (including genus and species) containing the PVCP-PIP.

(ii) The name of the virus from which the coat protein gene was derived.

(iii) The name of the virus(es) to which resistance is conferred.

(iv) When available, a unique identifier.

5. By revising § 174.480 to read as follows:

§ 174.480 Scope and purpose.

This subpart lists the inert ingredients that may be used in a plant-incorporated protectant listed in subpart B of this part and whose residues are either exempted from the requirement of a tolerance under FFDCA or no tolerance would otherwise be required.

6. By adding § 174.486 to read as follows:

§ 174.486 Inert ingredients that may be used with PIPs in certain plants.

The following must be used in a plant that satisfies § 174.27(a) in order to be exempt from the requirements of FIFRA.

(a) *Beta*-D-glucuronidase (GUS) from *Escherichia coli* and the genetic material necessary for its production.

(b) Neomycin phosphotransferase II (NPTII) and the genetic material necessary for its production.

(c) Phosphomannose isomerase (PMI) and the genetic material necessary for its production.

(d) CP4 enolpyruvylshikimate-3-phosphate (CP4 EPSPS) and the genetic material necessary for its production.

(e) Glyphosate oxidoreductase (GOX or GOXv247) and the genetic material necessary for its production.

(f) Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production.

(g) Partial tetracycline resistance gene under the control of a bacterial promoter as present in papaya line 55–1.

[FR Doc. E7–7297 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0643; FRL–8100–5]

RIN 2070–AD49

Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act for Residues of Plant Virus Coat Proteins that are Part of a Plant-Incorporated Protectant (PVC-Proteins); Supplemental Proposal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to exempt from the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 requirement of a tolerance, residues of coat proteins from viruses that naturally infect plants that humans consume when such coat proteins are produced in living plants as part of a plant-incorporated protectant (PIP) and the criteria proposed for this exemption are met. EPA believes there is a reasonable certainty that no harm will result from aggregate exposure to such residues, including all anticipated dietary exposures and all other exposures for which there is reliable information. This proposed exemption would eliminate the need to establish a maximum permissible level in food for these residues.

DATES: Comments must be received on or before July 17, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0643, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.
- *Instructions*: Direct your comments to docket ID number EPA–HQ–OPP–

2006–0643. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this docket facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Melissa Kramer, Hazard Assessment Coordination and Policy Division (7202M), Office of Science Coordination and Policy, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8497; fax number: (202) 564–8502; e-mail address: *kramer.melissa@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Document Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market PIPs. Potentially affected entities may include, but are not limited to:

- Pesticide and other agricultural chemical manufacturing (NAICS code 32532), e.g., establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals.
- Food manufacturing (NAICS code 311), e.g., establishments primarily engaged in the manufacturing of food or feed.
- Crop production (NAICS code 111), e.g., establishments primarily engaged in growing crops, plants, vines, or trees and their seeds.
- Colleges, universities, and professional schools (NAICS code 611310), e.g., establishments of higher learning which are engaged in development and marketing of virus-resistant plants.
- Research and development in the physical, engineering, and life sciences (NAICS code 54171), e.g., establishments primarily engaged in conducting research in the physical, engineering, or life sciences, such as agriculture and biotechnology.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions of 40 CFR part 174. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Docket*. EPA has established a docket for this action under docket ID number EPA–HQ–OPP–2006–0643. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this docket facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Proposing?

EPA is proposing to exempt the following from the FFDCA section 408 requirement of a tolerance: Residues of coat proteins from viruses that naturally infect plants that humans consume as part of a normal diet, including any metabolites or degradates of those coat proteins, when such coat proteins are produced in living plants as part of a PIP and the criteria proposed for this exemption are met. The proposed criteria are intended to clearly identify and exempt only those residues for which a long history of safe exposure and consumption can support exemption. EPA believes there is a reasonable certainty that no harm will result from aggregate exposure to such residues, including all anticipated dietary exposures and all other exposures for which there is reliable information. This proposed exemption would eliminate the need to establish a maximum permissible level in food for these residues.

III. What is the Agency's Authority for Taking this Action?

EPA is proposing to establish this tolerance exemption on its own initiative under sections 408(e) and (c) of FFDCA, 21 U.S.C. 346a(c) and (e). Under FFDCA section 408, EPA regulates pesticide chemical residues by establishing tolerances limiting the amounts of residues that may be present in or on food or by establishing exemptions from the requirement of a tolerance for such residues. Food includes articles used for food or drink by humans or animals. A food containing pesticide residues may not be moved in interstate commerce without an appropriate tolerance or an exemption from the requirement of a tolerance.

Section 408 of FFDCA applies to all ''pesticide chemical residues,'' which are defined as residues of either a ''pesticide chemical'' or ''any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)). FFDCA defines ''pesticide chemical'' as: ''any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide'' (21 U.S.C. 321(q)(1)). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 2(u) defines ''pesticide'' as: ''(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer. . .'' (7 U.S.C. 136(u)). Under FIFRA section 2(t), the term ''pest'' includes: ''(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism. . . which the Administrator declares to be a pest. . .'' subject to certain exceptions (7 U.S.C. 136(t)).

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Section 408(e)(1)(C) of FFDCA also grants EPA the authority to establish ''general procedures and requirements to implement this section'' (21 U.S.C. 346a(e)(1)(C)).

IV. Context

A. What is the Relationship of this Proposal to Other Regulatory Requirements under FIFRA and FFDCA?

When the genetic material that encodes an entire or a portion of a plant virus coat protein is introduced into living plants with the intention of preventing or mitigating viral disease in the plants, the genetic material and any substances produced from the genetic material constitute a type of pesticide termed a ''plant virus coat protein plant-incorporated protectant'' or ''PVCP-PIP.'' PVCP-PIPs meet the FIFRA section 2(u) definition of ''pesticide'' because they are introduced into plants with the intention of ''preventing, destroying, repelling, or mitigating any pest. . .'' (7 U.S.C. 136(u)) and plant viruses meet the FIFRA section 2 definition of ''pest'' (7 U.S.C. 136(t)). PVCP-PIPs are considered pesticide chemicals under FFDCA which defines a ''pesticide chemical'' as ''any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.'' As such, residues of PVCP-PIPs in or on food (hereinafter simply ''in food'') are subject to FFDCA section 408.

Since PVCP-PIPs are a relatively newly described type of pesticide, the discussion in this unit provides information explaining how this FFDCA proposed action on residues of the plant virus coat protein portion of a PVCP-PIP (called here the ''PVC-protein'') would affect the FFDCA and FIFRA status of the complete PVCP-PIP. To this end, several pieces of information are presented: A description of the anticipated residues of PVCP-PIPs; a discussion of the FFDCA status, either current or proposed, of all anticipated PVCP-PIP residues; a discussion of what would be considered in determining the FFDCA status of the complete PVCP-PIP; and a discussion of how the FFDCA status of PVCP-PIP residues relates to the FIFRA status of the PVCP-PIP.

1. *What are the components of a PIP*? A PIP is defined at 40 CFR 174.3 as ''a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.''

2. *What are the anticipated residues of PVCP-PIPs*? Based on the definition of a PIP, EPA anticipates residues of a PVCP-PIP would include residues of any PVC-protein; the nucleic acids associated with the PVCP-PIP, e.g., the genetic material encoding the PVC-protein; and any inert ingredient as defined for PIPs at 40 CFR 174.3. Each of these three classes of residues will also include any metabolite and degradate of that class in accordance with FFDCA section 201 that defines a ''pesticide chemical residue'' as ''a residue in or on raw agricultural commodity or processed food of (A) a pesticide chemical; or (B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)).

3. *What is the FFDCA status of each identified class of residues*? For the complete PVCP-PIP to be exempt from FFDCA section 408, all three classes of PVCP-PIP residues listed above must be exempt, i.e., residues of the PVC-protein, the nucleic acids associated with the PVCP-PIP, and any inert ingredient as defined for PIPs at 40 CFR 174.3. The units below discuss the status of residues of the PVC-protein under this proposed action, the status of residues of the nucleic acids associated

with the PVCP-PIP, and the status of residues of inert ingredients.

i. *Residues of PVC-proteins*. Residues in this category consist of residues of the PVC-protein and any metabolites or degradates of that protein. This proposal would exempt from tolerance requirements residues of PVC-proteins that meet certain criteria.

Coat proteins are those substances that viruses produce to encapsulate and protect the viral nucleic acid and to perform other important tasks for the virus, e.g., assistance in viral replication, movement within the plant, and transmission of the virus from plant to plant by insects (Ref. 1). Current scientific information suggests that prevention or mitigation of disease by some PVCP-PIPs may be protein-mediated because for certain PVCP-PIPs efficacy is correlated with the concentration of coat protein produced by the transgene (Ref. 2). In protein-mediated resistance, the coat protein is thought to impede the infection cycle by interfering with the disassembly of infecting viruses (Ref. 3). In such cases, EPA would consider the PVC-protein to be the pesticidal substance. Residues of such PVC-proteins and their metabolites and degradates that meet the proposed criteria would be covered by this proposal.

In transgenic plants employing a second mechanism of resistance called post-transcriptional gene silencing (PTGS), prevention or mitigation of viral disease is not correlated with the level of PVC-protein expression. Indeed, virus resistance can occur even when a coat protein gene expresses untranslatable RNA sequences and no PVC-protein is detected. In PTGS, RNA fragments appear to be pesticidal substances (Ref. 3). (See Unit II.E. of the companion document published elsewhere in this **Federal Register** for a more detailed description of PTGS.) Even when PTGS is the mechanism of resistance, any PVC-protein that might be produced is part of the PVCP-PIP. Residues of such PVC-proteins and their metabolites and degradates that meet the proposed criteria are also covered by this proposal.

ii. *Residues of nucleic acids*. Residues in this category include residues of the genetic material necessary for the production of the pesticidal substance and the genetic material for any inert ingredient as defined at 40 CFR 174.3. Residues in this category would also include residues of any nucleic acids effecting the pesticidal action of the PVCP-PIP, e.g., residues of nucleic acids involved in PTGS.

''Nucleic acids'' are defined at 40 CFR 174.3 as ''ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil; polymers of the deoxyribose-5'-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5'-monophosphates of uracil, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.'' Nucleic acids are currently exempt from FFDCA tolerance requirements. See 40 CFR 174.475 and 66 FR 37817 (July 19, 2001) (FRL–6057–5). EPA is not proposing to amend this exemption.

iii. *Residues of any inert ingredient*. Residues in this category consist of residues of any inert ingredient that is part of a PVCP-PIP and any metabolite or degradate of an inert ingredient. An inert ingredient for a PIP is defined at 40 CFR 174.3 as ''any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient.''

A tolerance or tolerance exemption is required for residues of any substance in food that meets the 40 CFR 174.3 definition of an inert ingredient (e.g., a selectable marker intentionally introduced into the plant as part of a PVCP-PIP such as a protein conferring resistance to an herbicide). Part 180 and part 174, subpart W, of 40 CFR list inert ingredients for which tolerance exemptions have been established. If an inert ingredient is not listed at part 180 or part 174, subpart W, an applicant would need to petition the Agency in accordance with 40 CFR 180.7 to obtain a tolerance or tolerance exemption for residues of that particular inert ingredient in order for food containing residues of the PVCP-PIP to move in interstate commerce—even if all other residues of the PIP are exempt.

4. *What is the relationship between the FIFRA status of a PVCP-PIP and the FFDCA status of its residues*? A tolerance exemption does not exempt a PVCP-PIP from FIFRA regulation. However, in order for a PVCP-PIP in food plants to be exempted from FIFRA regulation, a tolerance exemption must exist for all residues associated with a PVCP-PIP or FFDCA requirements must be otherwise met. (See the general qualification for exemption under FIFRA at 40 CFR 174.21(b).) The FIFRA status of a PVCP-PIP is determined based on factors in addition to FFDCA section 408 considerations because FIFRA requires the Agency to consider additional risk and benefit issues beyond those addressed under section 408 of FFDCA. Concurrently with this proposed FFDCA exemption, the Agency is publishing a proposal under which PVCP-PIPs might meet the general qualification for FIFRA exemption at 40 CFR 174.21(a) based on different criteria than the criteria in this proposal.

B. What is the History of this Proposal?

1. *Scientific input*. EPA sponsored (or cosponsored with other Federal agencies) six conferences relevant to development of this proposed rule: On October 19–21, 1987, a meeting on ''Regulatory Considerations: Genetically-Engineered Plants'' at Cornell University in Ithaca, NY; on September 8–9, 1988, a ''Transgenic Plant Conference'' in Annapolis, MD; on November 6–7, 1990, a conference on ''Pesticidal Transgenic Plants: Product Development, Risk Assessment, and Data Needs'' in Annapolis, MD; on April 18–19, 1994, a ''Conference on Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops'' in Annapolis, MD; on July 17–18, 1997, a ''Plant Pesticide Workshop'' in Washington, DC; and on December 10–12, 2001, a conference on ''Assessment of the Allergenic Potential of Genetically Modified Foods'' in Chapel Hill, NC. Information from these conferences has been incorporated as appropriate in development of this proposed rule.

EPA has requested the advice of two scientific advisory groups at five meetings while developing its approach to PIPs. On December 18, 1992, EPA convened the FIFRA Scientific Advisory Panel (SAP) to review a draft policy on PIPs (then called plant-pesticides) and to respond to a series of related questions posed by the Agency dealing primarily with EPA's approach under FIFRA. On July 13, 1993, EPA requested the advice of a Subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) on a series of scientific questions dealing with EPA's approach to PIPs under FFDCA. On January 21, 1994, EPA asked for advice on the Agency's approach to PIPs under both statutes at a joint meeting of the SAP and the BSAC. To evaluate more recent scientific advances, EPA again brought these issues to the SAP on October 13–14, 2004. On December 6–8, 2005, EPA requested the SAP to respond to a series of scientific

questions related to this proposal. EPA carefully considered advice from all five meetings in the development of this proposed rule.

2. **Federal Register** *documents*. The history of this proposal consists of the original proposed exemption that appeared in the November 23, 1994 **Federal Register** (59 FR 60545) (FRL–4755–4), a supplemental document that appeared in the May 16, 1997 **Federal Register** (62 FR 27149) (FRL–5716–6), and a supplemental document which appeared in the July 19, 2001**Federal Register** (66 FR 37855) (FRL–6760–4).

i. *November 23, 1994*. EPA published a package of five separate documents in the November 23, 1994 **Federal Register** which described EPA's policy and proposals for PIPs under FIFRA and FFDCA (59 FR 60496, 60519, 60535, 60542, and 60545). In one of these documents (59 FR 60545), EPA proposed to exempt from the requirement of a tolerance, residues of plant virus coat proteins produced and used in living plants as a plant-incorporated protectant (then called a plant-pesticide). The proposed exemption from the requirement of a tolerance read as follows:

''Residues of coat proteins from plant viruses, or segments of the coat proteins, produced in living plants as plant-pesticides are exempt from the requirement of a tolerance'' (59 FR 60547).

ii. *May 16, 1997*. In August of 1996, Congress enacted the Food Quality Protection Act (FQPA), which amended FFDCA and FIFRA. On May 16, 1997, EPA published a supplemental document in the **Federal Register** (62 FR 27149) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA apply to the proposed exemption from the requirement of a tolerance for residues of PVC-proteins.

In that supplemental document, EPA explained how most of the substantive factors that the amended FFDCA requires EPA to consider in evaluating pesticide chemical residues had been considered in the Agency's 1994 proposed tolerance exemption. Even though the Agency may not have used the terminology specified in FQPA, EPA did take into account most of the same factors in issuing its 1994 proposal to exempt residues of PVC-proteins, or segments of such proteins, from FFDCA tolerance requirements. EPA therefore sought comment on the requirements imposed by FQPA that the Agency had not addressed in its 1994 proposal, specifically:

a. EPA's conclusion that there are no substances outside of the food supply that may have a cumulative toxic effect with residues of PVC-proteins,

b. EPA's conclusion that there are no substances outside of the food supply to which humans might be exposed through non-occupational routes of exposure that are related via a common mechanism of toxicity to residues of PVC-proteins,

c. Any available information on PVC-proteins causing estrogenic effects,

d. EPA's rationale, described in greater detail, for concluding that PIPs are likely to present a limited exposure of pesticidal substances to humans in which the predominant, if not the only, route of exposure will be dietary, and

e. EPA's rationale, described in greater detail, for concluding that the Agency's analysis concerning the dietary safety of food containing PVC-proteins applies to infants and children as well as adults.

iii. *July 19, 2001*. In July of 2001, EPA published a supplemental document in the **Federal Register** (66 FR 37855) to provide the public with additional opportunity to comment on the FIFRA and FFDCA exemptions for PIPs that the Agency proposed in 1994 but had not yet finalized by 2001. EPA also requested comment on the information, analyses, and conclusions pertaining to PVCP-PIPs contained in the NRC report entitled ''Genetically Modified Pest-Protected Plants: Science and Regulation'' (Ref. 4). In addition, the public was given an opportunity to comment on a clarification of the language in the original 1994 proposal on PVCP-PIPs that EPA was considering in response to public comment. The purpose of the clarification was to circumscribe more clearly those residues proposed for exemption.

The documents, including associated public comments, and the reports of the meetings described above are available in the public dockets established for each of the associated rulemakings as described in Unit XII.B.

This proposed rule completely supersedes these previous proposals. EPA does not intend to respond to comments submitted on those proposals. Thus, individuals who believe that any comments submitted on any of the earlier proposals remain germane to this proposal should submit them (or relevant portions) again during this comment period.

C. Rationale Supporting the Proposed FFDCA Tolerance Exemption

EPA's base of experience with viruses infecting food plants has led the Agency to draw three conclusions on which it is relying to support this proposed tolerance exemption for residues of PVC-proteins in food. First, virus-infected plants have always been a part of the human and domestic animal food supply. Most crops are frequently infected with plant viruses, and food from these crops has been and is being consumed without adverse human or animal health effects. Second, plant viruses are not infectious to humans, including children and infants, or to other mammals. Third, plant virus coat proteins, while widespread in food, have not been associated with toxic or allergenic effects to animals or humans. These conclusions are derived from a base of experience and information sufficient to support this proposed tolerance exemption.

1. *Always been part of food supply without adverse effects*. Virus-infected food plants have always been a part of the human and domestic animal food supply (Refs. 5, 6, 7, 8, 9, and 10). Most plants are infected by at least one virus, and components of plant viruses, including coat proteins, are often found in the produce of crop plants. For example, at the beginning of this century virtually every commercial cultivar of potatoes grown in the United States and Europe was infected with either one or a complex of potato viruses (Ref. 10). Even plants that show no disease symptoms are often found to be infected with viruses (Refs. 9 and 11). In addition, a common agricultural practice used since the 1920s for protection against viral disease involves intentionally inoculating healthy plants with a mild form of a virus in order to prevent infection by a more virulent form (Ref. 11). A recent analysis of viral sequences isolated from fecal samples of healthy humans showed the presence of large quantities of plant pathogenic viruses from 35 different plant virus species with evidence suggesting dietary origins for the most prevalent (Ref. 12). A great deal of information supports the ubiquitous appearance of plant viruses in foods, and to date there have been no reports of adverse human or animal health effects associated with consumption of plant viruses in food.

The National Research Council (NRC) observed in its 2000 report that ''[h]uman or animal consumption of plants with viral coat proteins is widely considered to be safe, on the basis of common exposure to these types of proteins in nontransgenic types of food'' (Ref. 4). The FIFRA SAP addressed the issue of dietary risk at its December 18, 1992 meeting (Ref. 13). The SAP stated, ''Since viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic

plants, and there has been a long history of 'contamination' of the food supply by virus coat protein, there is scientific rationale for exempting transgenic plants expressing virus coat protein from the requirement of a tolerance.'' The FIFRA SAP again discussed PVC-proteins on October 11–13, 2004, and ''agreed that (because of the human history of consuming virus infected food), unaltered PVCPs do not present new dietary exposures'' (Ref. 14). The 2005 SAP also agreed that ''[h]istorically, virus infected plants have been a part of the human and domestic animal food supply without adverse human or animal health effects'' (Ref. 15).

In general, EPA anticipates that dietary exposure through human and animal consumption of plants containing residues of PVC-proteins that would qualify for the proposed exemption will be similar to or less than the dietary exposure to plant virus coat proteins currently found in food plants naturally infected with viruses. Experiments have shown the amount of PVC-protein found in plants containing a PVCP-PIP to be as much as one hundred- to one thousand-fold lower than the amount of plant virus coat protein found naturally in virus-infected plants, even when the resistance is believed to be mediated by the PVC-protein itself (Refs. 8 and 16). The difference in amount of PVC-protein present is even more marked for virus-resistant plants employing resistance mediated by RNA. In such cases, little to no detectable coat protein is produced in a plant containing a PVCP-PIP (Refs. 3 and 17). Such information conforms to information EPA has received from the scientific advisory groups the Agency has consulted (see Unit IV.B.1.). Although the Agency believes that the PVC-proteins which qualify for this proposed tolerance exemption are safe at any level given the long history of human dietary exposure to high levels of such proteins, the anticipated low levels of exposure to PVC-proteins in food lend additional support to this proposed exemption.

2. *Not infectious to humans*. Any virus/host relationship is characterized by a high degree of specificity (Ref. 8). Plant viruses usually infect plants only within a certain taxonomic group and are unable to infect humans or other vertebrates (Refs. 18 and 19). Cellular machinery for processing genetic material is highly specific. For example, plant viruses are unable to recognize and attach to the specific sites on mammalian cells needed to penetrate the cell membrane, and plant viruses cannot be processed by mammalian cellular machinery. Plant viruses therefore do not and cannot infect mammals and other vertebrates. In addition, multiple virus components in addition to the coat protein have a role in and are necessary for plant infection. Plant viral coat proteins alone are not infectious to plants, and whole, intact plant viruses are not infectious to humans. Therefore, it is reasonable to assume that a single component of plant viruses, e.g., the PVC-protein, will not be infectious to humans.

3. *No toxic or allergenic effects to animals or humans*. Humans and domestic animals have been and are exposed to plant viruses in the food supply because most crops are frequently infected with plant viruses. Food from these crops has been and is being consumed with no indication of human or animal toxicity related to plant virus infections. Additionally, in experiments where purified plant virus preparations have been injected into laboratory animals, no adverse effects have been reported (Ref. 17). Furthermore, the Agency is not aware of any coat protein from a virus that naturally infects plants that has been identified as a food allergen for humans. Finally, the amount of PVC-protein likely to be found in food is anticipated to generally be lower than the amount of virus coat protein found in food naturally infected with plant viruses (as discussed in Unit IV.C.1.).The 2005 SAP questioned whether an increased propensity for allergies in humans affects the relevance of the history of safe use to the current safety of virus coat proteins. Several studies have documented a general increase in atopy in human populations; these studies show that over the last several decades there has been an increasing proportion of human populations that have an allergic sensitization to particular allergens (Refs. 20, 21, and 22). However, there is no reason to believe that PVC-proteins in the environment would have any impact on this phenomenon. EPA is aware of no evidence that previously nonallergenic substances are now able to elicit an immune response, and no plant virus coat proteins have ever been identified as allergens. Moreover, the amount of plant virus coat protein in the environment is not expected to increase due to the use of PVCP-PIPs. On the contrary, PVCP-PIPs generally express PVC-protein at levels below that found in natural virus infections, and the virus-resistant phenotype conferred by PVCP-PIPs should significantly reduce levels of natural virus infection in plants, thereby decreasing the amount of plant virus coat protein in the environment where PVCP-PIPs are deployed.

D. Key Issue: Determination of Natural Virus Variation

A key issue facing EPA in developing this exemption is how to clearly describe for regulatory purposes those PVC-proteins that are within the range of naturally occurring plant virus coat proteins and to which the rationale discussed in Unit IV.C. therefore applies. If a plant virus coat protein gene is isolated in nature and not modified, the PVC-protein would clearly be within the range of natural variation. However, many coat protein genes are modified in creating a PVCP-PIP, e.g., to increase product efficacy or allow appropriate expression in the plant. Some of these modifications may affect a PVC-protein, although most of these variations would not be expected to differ significantly (e.g., in terms of toxicity or allergenicity) from the naturally occurring coat protein. In fact, given the considerable variation in naturally occurring viral coat proteins, it is also possible that naturally occurring plant viruses exist with some of the minor modifications that could conceivably be introduced into PVC-proteins.

However, EPA's task of defining this variation is complicated by the variable nature of plant virus genomes and the fact that the full extent of variation for even a single plant virus is currently unknown. Sequencing of plant virus genomes has revealed that a large number of variants exist within most populations of both RNA and DNA viruses. Due to this inherent heterogeneity in virus populations, they are often described as ''quasispecies'' that exist as a pool of different sequences varying around a consensus sequence (Refs. 23, 24, and 25).

Genetic variation in virus populations arises due to several processes including mutation, recombination, and reassortment. Mutation is a change in the genetic material that most commonly occurs when replication errors lead to incorporation of an incorrect nucleotide into the daughter sequence (Ref. 26). New virus variants are also generated by recombination, the natural process that occurs during replication of DNA or RNA whereby new combinations of genes are produced. Recombination is more likely to occur the more closely related viruses are, but recombination between different viral species is also believed to occur (Refs. 27 and 28). Evidence of past recombination having led to the creation of new DNA and RNA viruses has been

found in a number of different groups including bromoviruses (Ref. 29), caulimoviruses (Ref. 30), luteoviruses (Ref. 31), nepoviruses (Ref. 32), cucumoviruses (Ref. 33), and geminiviruses (Refs. 27 and 34). Sequence analysis of viruses from the family Luteoviridae indicated that this family has evolved via both intra- and inter-familial recombination (Ref. 35). In viruses with segmented genomes, variation may also be caused by reassortment whereby entire segments are exchanged between viruses (Ref. 36).

Attempts to describe the range of variation for naturally occurring plant virus coat proteins are complicated not only by variation within species but also by variation among species (See Ref. 37 for review). For example, cucumber mosaic cucumovirus (CMV) has a relatively high degree of variation (Ref. 38) compared to tobacco mild green mosaic tobamovirus (Ref. 39). The greater variability in CMV would be expected based on the relatively wide host range and relatively high recombination rate of this virus. Such wide-ranging, inherent variability confounds attempts to establish meaningful estimates of normal variability for coat proteins of plant viruses as a group.

A large number of viral coat protein sequences are currently available in the literature and in public sequence repositories, e.g., the National Center for Biotechnology Information. However, EPA has concluded that no single standard could capture the degree of variation across all viruses, and hundreds of plant viruses have been identified to date (Ref. 40). It would be at best impractical for EPA to describe individually for all virus groups all potential modifications that would produce a PVC-protein that falls within the range of natural variation given the vast (and yet still incomplete) amount of data that currently exists. The 2005 SAP concurred with these conclusions: ''Currently, it is extremely difficult to identify modifications that would be expected to be 'within the range of natural variation for all virus families'. This would require prior knowledge of the natural variation limits of the individual PVC proteins, which is not available. Specific modifications can be identified that would raise potential concerns, but it is not clear that it is possible to create a comprehensive list of these changes for all virus families'' (Ref. 15).

At the present time, insufficient information exists to develop a standard that would describe *a priori* the degree to which a PVC-protein could be modified and yet still remain within the natural variability of plant virus coat proteins found in virus populations either generally or for any species in particular. In light of this, and relying extensively on the advice of the 2005 FIFRA SAP meeting (Ref. 15), EPA has developed two proposals to exempt PVC-protein residues from the requirement of a tolerance:

1. A categorical exemption for a subset of PVC-proteins based on developer self-determination that the encoded PVC-protein is virtually unmodified when compared to an entire unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part, and

2. An exemption for more extensively modified proteins that is conditional on an Agency determination after review that the encoded PVC-protein is minimally modified when compared to an unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part.

E. Structure of the Proposed FFDCA Tolerance Exemption

1. *Proposed categorical exemption.* Under the proposed exemption at § 174.477(a), when the encoded PVC-protein is virtually unmodified when compared to an entire unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part, the residues of the PVC-protein would be exempt from the requirement of a tolerance without Agency review. If the PVC-protein is expressed from a plant virus coat protein gene that was isolated from a virus found naturally in a food plant in the United States and was not modified, the PVC-protein would meet this criterion. Additionally, a PVC-protein would meet this criterion if the developer has evidence showing it has an amino acid sequence that is virtually unmodified when compared to an unmodified plant virus coat protein sequence from a virus that naturally infects plants that humans consume, e.g., as found in a database. Although EPA cannot *a priori* identify all existing natural coat protein variants, the requirement of being virtually unmodified when compared to an entire unmodified coat protein ensures that the exempted PVC-protein falls within the existing base of experience on which the proposed exemption relies.

EPA intends, with the requirement that the PVC-protein be virtually unmodified when compared to ''an entire unmodified coat protein,'' to exclude from the categorical exemption residues of modified PVC-proteins, e.g., PVC-proteins containing insertions, deletions, or amino acid substitutions (except as described below by the definition of virtually unmodified), as well as chimeric PVC-proteins that are encoded by a sequence constructed by fusing portions of two or more plant virus coat protein genes. EPA is proposing to exclude such PVC-proteins from the categorical exemption because of advice from the 2005 SAP that insufficient information exists at this time to allow EPA to describe *a priori* a single standard articulating which of these types of changes would be consistently expected to fall within the natural range of variation of viruses and/or which types of changes could be determined not to affect toxicity or allergenicity without any EPA review (see Unit IV.D.).

The Agency proposes to define the term ''unmodified'' to mean, ''having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus.'' The Agency is considering several options for defining the term virtually unmodified. Under this proposal, any virtually unmodified PVC-protein would qualify for a tolerance exemption without Agency review. Under one option, this term would mean, ''having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus, except for the addition of one or two amino acids at the N- and/or C-terminus other than cysteine, asparagine, serine, and threonine and/or the deletion of one or two amino acids at the N- and/or C-terminus.'' As noted by the 2005 SAP, the terminal ends of a protein ''are the least structurally constrained regions of a protein. As such, the ends can be thought of as being essentially 'unstructured,' and therefore unlikely to serve as allergenic epitopes or to make major contributions to the overall structure of the molecule. Addition (or deletion) of one or two amino acids is unlikely to change this.'' However, the SAP also noted the possibility that the addition of amino acids such as cysteine with side chains that could promote cross-linking or aggregation between molecules or other amino acids that can serve as sites for post-translational modifications should be evaluated on a case-by-case basis (Ref. 15). EPA has identified cysteine, asparagine, serine, and threonine as the amino acids containing side chains that could promote cross-linking or serve as sites for post-translational modifications. EPA therefore excludes the addition of these amino acids from the proposed definition of virtually unmodified. The 2005 SAP report mentioned alanine as an amino acid involved in

glycosylation; however, EPA has found no evidence that alanine is involved in glycosylation or promotes cross-linking. The Agency has therefore not excluded the addition of alanine under the definition of virtually unmodified.

The Agency is also considering two possible changes to the above definition of virtually unmodified. The first change would remove the restriction that cysteine, asparagine, serine, or threonine may not be added to the naturally occurring protein. Under this alternative, a PVC-protein would qualify for the tolerance exemption without Agency review if it has an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus except for the addition, substitution, or deletion of one or two amino acids at the N- and/or C-terminus. The rationale underlying such an alternative would be that addition of any amino acid to the N- or C-terminus, e.g., including those that could be glycosylated, is unlikely to introduce any concern. In order for an amino acid to be glycosylated, a protein must also have a specific enzyme recognition site. The creation of such a recognition site by the addition, substitution, or deletion of one or two amino acids, particularly at the end of the protein, is expected to be extremely rare because it would involve randomly producing a set of amino acids involved in a specific interaction. The addition of an amino acid with a side group that is capable of forming a covalent bond, e.g., cysteine, is likewise unlikely to alter the safety of the expressed protein. Such amino acid residues would typically be unavailable due to interactions that occur within the protein's normal folding conformation. A plant virus coat protein is large enough that protein functionality or chemistry would not be dramatically different from a PVC-protein that is identical except for its possessing two additional amino acids at the N- and/or C-terminus. As previously stated, the 2005 SAP said the terminal ends of a protein ''are the least structurally constrained regions of a protein'' (Ref. 15). In addition, virus coat proteins are self-assembling, structural proteins that contain elements necessary for continual infection and replication of the entire virus particle. As a structural element of a virus particle, one important function of the coat protein is the ability to interact with itself to form stable particles. Most if not all plant virus coat proteins will naturally aggregate (Refs. 41 and 42), so the addition of amino acids that could promote cross-linking or aggregation would not fundamentally change the nature of the PVC-protein.

The second change to the above definition of *virtually unmodified* that the Agency is considering would allow truncated proteins to fall under the definition. Under this alternative, a PVC-protein would be exempt without Agency review if it has an amino acid sequence that is identical to *a single contiguous portion* of a coat protein of a naturally occurring plant virus, except for the addition or substitution of one or two amino acids at the N- and/or C-terminus of the single contiguous portion other than cysteine, asparagine, serine, and threonine. EPA intends that ''identical to a single contiguous portion'' would exclude proteins with internal modifications. The rationale underlying such an alternative would be that truncated PVC proteins have been reported to occur in nature (Ref. 43), as pointed out by the 2005 SAP. ''Naturally occurring truncated forms of the PVCs could be generated by post-transcriptional and translational events, including incomplete translation due to routine errors causing a ribosome to dissociate from an mRNA, post-translational processing, the presence of a mutation that introduces a premature stop codon, or by infrequent translation initiation at downstream AUGs. . . . Whether the truncation is at the N- or C-terminus is not relevant to allergenicity or toxicity'' (Ref. 15). The SAP also said, ''Determining whether PVC-proteins containing terminal deletions, or any other modifications, are within the range of natural variation would require the development of a database of the natural variation and truncated forms of PVC-proteins that occur naturally. If a truncated PVC-protein does fall within the range of natural variation, the likelihood of increased toxicity and allergenicity would be low'' (Ref. 15). However, such a database may not be necessary because the potential for toxicity and allergenicity of a whole plant virus coat protein is low enough that the likelihood of a truncated form of such a protein being toxic or allergenic would not rise to the level requiring regulation. Such a change in toxicity or allergenicity would require the truncation to expose new allergenic epitopes or specific recognition/binding sites in the protein that could make the protein toxic, but there is no indication that plant virus coat proteins possess such regions. The 2000 SAP indicated that ''[i]n general, peptide fragments that result from the breakdown of proteins are less toxic than the intact protein'' (Ref. 44).

Either of the changes discussed above could be adopted alone, or both could be adopted together. If EPA adopts both changes, a PVC-protein would be exempt from the requirement of a tolerance without Agency review if it has an amino acid sequence that is identical to *a single contiguous portion* of a coat protein of a naturally occurring plant virus; except for the addition or substitution of one or two amino acids at the N- and/or C-terminus of the single contiguous portion.

EPA is proposing to require that the virus used as the source of the coat protein sequence ''naturally infects plants that humans consume'' as an additional means of ensuring the proposed exemption is limited to PVCP-PIPs that fall within the base of experience discussed previously in this unit. This phrase is intended to limit the proposed exemption to residues of PVC-proteins that are already part of the normal human diet as naturally occurring plant virus coat proteins or are minimally modified from such proteins (see Unit IV.C.1.). The exemption would not extend to PVC-proteins encoded in part by sequences from animal or human viruses.

EPA proposes to define the term ''naturally infect'' to mean ''infect by transmission to a plant through direct plant-to-plant contact (e.g., pollen or seed), an inanimate object (e.g., farm machinery), or vector (e.g., arthropod, nematode, or fungus). It does not include infection by transmission that occurs only through intentional human intervention, e.g., manual infection in a laboratory or greenhouse setting.'' The Agency is proposing this definition specifically to exclude transmission that occurs only through intentional human intervention because such transmission would have little relevance to normal human dietary exposure. Viruses that may be able to infect plant species in a laboratory or greenhouse setting through manual infection may not ever infect such species in nature. EPA intends to include within this definition viruses that are likely to have been part of the human diet due to their ability to spread without intentional human intervention. EPA recognizes that humans may play an inadvertent role in infection (e.g., by transmitting the virus on farm machinery). Such unintentional (and often unavoidable) transmission can be an important means of virus transmission, leading to the presence of natural virus coat proteins in food plants that humans consume. EPA therefore includes this mode of transmission in the definition of naturally infect to encompass those viruses that would be expected to be at

least occasionally found in the plant and therefore be a normal constituent of the human diet. To further clarify that the proposed exemption applies only to coat proteins from plant viruses, EPA is specifically including the word ''plant'' as an adjective in the name, i.e., ''PVC-proteins'' are ''plant virus coat proteins.''

EPA has considered whether to limit the proposed exemption to PVC-proteins from PVCP-PIPs based on viruses that naturally infect the *particular* food plant in which the PVC-protein is expressed. EPA must address whether there would be any safety issues raised from exposure to PVC-proteins if the virus used to create the PVCP-PIP does not naturally infect the particular plant species into which the PVCP-PIP is inserted. A PVC-protein may be expressed in a food plant that the virus does not naturally infect when heterologous resistance to a particular virus is conferred through a different virus' coat protein gene (e.g., Ref. 45). However, the Agency believes such PVC-proteins could be safely exempted from tolerance requirements because these proteins would still reasonably be expected to be part of the normal diet as long as they naturally infect plants used as food. Based on their broad host range, plant viruses are known generally to infect a wide variety of plants that humans consume. People generally eat a broad range of food plants through which they would reasonably be expected to be exposed to a wide variety of plant virus coat proteins (Ref. 12). In addition, EPA is not aware that any plant viral coat proteins have been identified as allergens, so it is unlikely that a person with food allergies avoids a particular food plant because of an allergic reaction to a viral coat protein. Based on this rationale and in the absence of contravening evidence, EPA concludes that a PVC-protein expressed in a plant that is not normally infected by the virus from which the PVC-protein was derived would raise no safety issues as long as the corresponding virus infects other plants that are consumed by humans.

When EPA asked the 2005 SAP to comment on this issue, the Panel ''expressed some disagreement as to whether the level of risk associated with human exposure to any protein is solely dependent on the protein itself. One Panel member concluded that the host producing the protein is of secondary importance. Others expressed concern related to expression of PVC-proteins in plants that are known to be highly allergenic such as peanut'' (Ref. 15). The Panel did not elaborate on the rationale for such concerns at this point in the SAP report. EPA's interpretation of this issue is that the concern is due to the possibility, articulated elsewhere in the Panel report, that ''the changed infectivity status of the plant may also induce changes in the overall protein expression pattern of the plant. Thus, in various tissues of the plant, natural plant proteins that have been identified as allergens may be expressed to a different, and in some cases, higher extent compared to a non-infected or a virus-infected plant without PVCP-PIP. In particular, pathogenesis-related (PR) proteins are known to be very inducible, and their expression levels may vary many-fold. Several pathogenesis-related proteins have been described as allergens (Breiteneder et al. 2000 and 2004), most notably the major birch pollen protein Bet v1 (Breiteneder et al. 1989). An increased expression of PR-proteins in pollen could increase both the risk of sensitization and the risk of elicitation of allergic reactions'' (Refs. 15, 46, 47, and 48). This concern is distinct from the concern that EPA addressed above, namely that the PVC-protein itself may introduce an allergen into a food source where it is not anticipated to be found. The issue the SAP raised would generally be addressed by the Food and Drug Administration (FDA) in evaluating food composition. However, EPA has not found evidence that introduction of a PVCP-PIP would affect induction of PR proteins *per se*. PR proteins are a normal constituent of plants because plants express such proteins in response to environmental stresses, including virus infection, exposure to certain chemicals, and wounding. Some plant tissues even constitutively express such proteins, e.g., those likely to be attacked by pests or exposed to environmental stresses such as ultra-violet (UV) irradiation (Ref. 49). Moreover, given the large number and variety of pathogens (including viruses) encountered by plants in the field, and given differences in the virus-infectivity status of plants that occur naturally, humans consume varying amounts of PR proteins as part of the normal diet. The level found in plants containing a PVCP-PIP is therefore expected to be within the range of natural variation.

EPA has also considered whether a geographic limitation on this proposed categorical exemption would be necessary to ensure that the exemption extends only to residues that are part of the U.S. diet; i.e., that the proposed exemption would only extend to PVC-proteins that are part of a PVCP-PIP constructed from a virus that occurs naturally in the United States. EPA believes that such a limitation is unnecessary to ensure that the PVC-proteins proposed for exemption fall within the base of experience supporting the proposal. Humans have long consumed viruses infecting food plants with no adverse effects. Given the extent of modern market practices in which food is shipped globally for human consumption, human dietary exposure to all viruses that infect food plants is likely to occur broadly. The lack of any known adverse effects attributable to plant viruses suggests that plant virus coat proteins in the diet are safe to humans.

EPA has also considered whether additional conditions are necessary to ensure that the expression level of virtually unmodified PVC-proteins found in plants is no greater than the level of plant virus coat protein generally found in a natural virus infection. The 2005 SAP suggested that ''for both modified and unmodified proteins, the Agency might wish to consider. . . expression levels'' when determining whether to exempt a PVC-protein from tolerance requirements (Ref. 15). The SAP apparently based this suggestion on the assumption that EPA considered exposure level to be an important component of a PVC-protein risk assessment given that the Agency's background material for the Panel indicated that the dietary exposure to PVC-proteins is anticipated to be similar to or less than the dietary exposure to plant virus coat proteins currently found in food plants naturally infected with viruses. However, even though EPA addresses exposure level in evaluating safety (e.g., see Unit IV.C.1.), the Agency also believes that the PVC-proteins that qualify for this proposed exemption are safe at any level that could be produced in a plant. Humans have been exposed to plant virus coat proteins over long periods of time at varying and sometimes high levels, and to date there is no indication that any plant virus coat protein is an allergen or a toxin. The Agency therefore believes that the hazard associated with PVC-proteins that are virtually unmodified from natural plant viral coat proteins is sufficiently low that it does not rise to the level warranting regulation, even if in some cases exposure to a PVC-protein might be greater than the exposure to the corresponding natural plant virus coat protein. Nevertheless, the Agency regards the anticipated low levels of exposure through food to the PVC-proteins covered by this proposal as additional support for this proposed categorical exemption. According to the 2005 SAP, ''On a per cell basis, it is

almost certain that all viral gene products are expressed at higher levels in virus-infected than transgenic plants'' (Ref. 15).

2. *Proposed exemption conditional on Agency determination*. The Agency recognizes that product developers frequently modify the genetic material of a PVCP-PIP, e.g., in order to achieve greater efficacy (Ref. 50) and that most of these changes would be unlikely to result in proteins affecting potential dietary risk. However, the Agency cannot at this time articulate a criterion that would ensure all PVC-proteins with such modifications fall within the base of experience supporting the proposed exemption.

The question of how to objectively define criteria on which the regulated community may rely to determine *a priori* how much a virus coat protein may be modified and still fall within the range of natural variation is a key challenge. EPA first considered the question of how to describe residues that fall within the base of experience supporting exemption when the Agency issued its proposal on November 23, 1994 (59 FR 60539). In the July 19, 2001 supplemental notice (66 FR 37865), EPA again addressed the question of how to describe PVCP-PIPs that fall within the recognized base of experience supporting the proposed categorical exemption.

In October 2004, the FIFRA SAP was asked to consider the degree and ways a plant virus coat protein gene might be modified while still retaining scientific support for the idea that humans have consumed the products of such genes for generations and that such products therefore present no new dietary exposures (Ref. 14). They responded, ''There was no clear consensus on how much change would be necessary to invalidate this assumption, although there was general agreement that the appropriate comparison is to the range of natural variation in the virus population.'' The 2005 SAP also addressed this question. They concurred that, ''it is extremely difficult to identify modifications that would be expected to be 'within the range of natural variation for all virus families'. . . . Given the possible range of natural variations for PVC proteins, it would be appropriate to assess whether specific modifications are within natural variation limits of the PVC protein on a case-by-case basis'' (Ref. 15).

EPA believes that developing objectively defined criteria on which the regulated community could rely to determine whether a modified PVC-protein falls within the natural range of variation for a particular virus is not currently feasible because the Agency knows of no generally applicable, established baseline for what constitutes the range of natural variation of a virus. EPA thus does not believe that proposing an exemption that would allow developers to self-determine eligibility of modified PVC-proteins would be supportable. Rather, EPA is proposing that under proposed § 174.477(b), the residues of such a PVC-protein would be exempt only if the Agency determines after review that the encoded PVC-protein is minimally modified when compared to an unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part.

In determining whether a PVC-protein is minimally modified from a natural viral coat protein, EPA will consider first how similar the PVC-protein is to a natural viral coat protein by evaluating information on the PVCP-PIP genetic construct, PVC-protein deduced amino acid sequence, and biochemical characterization of the PVC-protein as expressed in the plant (e.g., molecular weight to evaluate potential post-translational modifications). EPA might also evaluate developer-submitted analyses that characterize the PVC-protein sequence relative to the range of natural coat protein variation found in public sequence databases. Those PVC-proteins determined to be similar to a natural viral coat protein would be further evaluated to determine whether the modified PVC-protein is as safe as an unmodified protein by considering information from an amino acid sequence comparison with known protein toxins and allergens. The type and extent of information that would need to be provided in order for EPA to determine whether a PVC-protein is minimally modified and therefore qualifies for the exemption would be determined on a case-by-case basis.

The 2005 SAP identified certain modifications that might raise potential concerns when considering if a protein is minimally modified, including ''the addition or removal of protease recognition sites, the addition or removal of cysteine residues involved in internal cross-links, the addition or removal of proline residues that act as secondary structure 'break points,' and the addition or removal of asparagines and alanines involved in glycosylation'' (Ref. 37). By contrast, the report identified ''[m]odifications such as single amino acid substitutions with biochemically similar amino acids that do not affect secondary or tertiary structure'' as potentially being of relatively little concern (Ref. 37). EPA would consider this guidance as appropriate in evaluating individual exemption petitions to determine whether a protein is minimally modified.

Regarding the 2005 SAP suggestion that EPA might wish to consider expression levels in determining whether to exempt a PVC-protein from tolerance requirements, the Agency believes that such an evaluation is not necessary to determine whether a PVC-protein is minimally modified. EPA would necessarily have to find such proteins to be similar to a natural viral coat protein in order for them to qualify for this proposed exemption. EPA believes that minimally modified PVC-proteins are safe at any level for the same reasons discussed above for virtually unmodified proteins (Unit IV.E.1.). In both cases, the hazard associated with PVC-proteins qualifying for this proposed tolerance exemption is sufficiently low that it does not rise to the level warranting regulation, even if in some cases exposure to a PVC-protein might be greater than the exposure to the corresponding natural plant virus coat protein. (However, see Unit XI. for a discussion of how exposure level could possibly be considered under the proposed exemption structure when reviewing minimally modified proteins.)

Under proposed § 174.477(b), the procedures for obtaining a determination that a PVC-protein fits under the tolerance exemption would be no different than those currently provided under the statute for obtaining a tolerance exemption. A person can file a submission requesting a determination (21 U.S.C. 346a(d)) of whether a particular PVC-protein fits under the tolerance exemption, or the Agency can initiate an action to issue a determination (21 U.S.C. 346a(e)). After a person files a submission under FFDCA section 408(d)(1) proposing that a particular PVC-protein falls under this exemption because it is minimally modified from a natural plant virus coat protein, FFDCA section 408(d)(3) requires that the Administrator determine whether a petition meets the requirements of the statute and publish a summary of the petition and other required information in the **Federal Register** within 30 days of making that determination. Alternatively, the Administrator may publish a notice of proposed rulemaking and provide a period of generally not less than 60 days for public comment. In either case, EPA will publish any final rule exempting a PVC-protein from the requirement of a tolerance in the **Federal Register** and allow 60 days for any person to file objections thereto (21 U.S.C. 346a(g)(2)).

Currently no fees would be associated with either the proposed categorical exemption under § 174.477(a) or the Agency's determination under proposed § 174.477(b) that a particular PVC-protein fits under the tolerance exemption.

For residues of a PVC-protein that would not qualify for this proposed exemption under either § 174.477(a) or (b) because the Agency cannot determine that the encoded PVC-protein is minimally modified from an unmodified coat protein from a virus that naturally infects food plants, an applicant may petition the Agency for an individual tolerance exemption under FFDCA section 408 (see also 40 CFR 180.7).

F. Tolerance Issues Associated with Unintended Protein Production when Virus Resistance is Mediated through Post-Transcriptional Gene Silencing

Section 408 of the FFDCA does not require a tolerance or tolerance exemption if residues will not be present in food moving in interstate commerce. However, with the exception of residues that meet the requirements proposed at § 174.477(a), the mere fact that a developer may not detect residues during product development will not protect the food from seizure if residues are subsequently found following commercialization, either because detection techniques improve or because the protein is unexpectedly produced. If such an event occurs and no tolerance exemption exists for residues of that PVC-protein (regardless of its safety), any food containing the PVC-protein residues would be adulterated and subject to seizure. In addition, any FIFRA exemption that may have been applicable for the PVCP-PIP would no longer be valid because 40 CFR 174.21(b) would no longer be satisfied. Any sale or distribution of such a PVCP-PIP would constitute sale and distribution of an unregistered pesticide, in violation of FIFRA section 12(a)(1).

The 2005 SAP suggested that the construction of certain PVCP-PIPs may offer a reasonable level of assurance that PVC-protein production would not occur, i.e., transgene insertions where the transcribed segment lacks an initiator codon or insertions of transcribed inverted repeat constructs that constitutively produce transcripts that are folded into double-stranded RNA as the immediate product of transgene transcription (Ref. 15). However, for other types of constructs, questions remain about circumstances under which PVC-protein might be detected and/or produced in food at some point after commercialization even though PVC-protein may not have been detected and/or produced during product development. For example, it is known that in some cases PTGS must be triggered before transgene RNA production can be effectively suppressed. Lindbo *et al.* (Ref. 51) used tobacco etch virus (TEV) to infect transgenic tobacco plants containing a TEV coat protein gene. Plants temporarily developed symptoms but were able to recover from infection. Recovered transgenic plant tissue showed significantly reduced levels of transgene mRNA, and PVC-protein was undetectable. However, plant tissues unchallenged with virus did express PVC-protein, suggesting that in at least some cases of PTGS-induced virus resistance, PVC-protein may be produced until virus infection occurs. Béclin et al. (Ref. 52) showed that in transgenic tobacco lines expressing a β-glucuronidase (uidA) transgene, suppression of transgene expression always occurs but is initiated at different plant developmental stages: Either 15 days after germination or 2 months post-germination. Prior to PTGS initiation, transgenic protein is expressed, suggesting that in at least some cases lack of protein production may only occur after a certain developmental stage is reached. Likewise, Pang *et al.* (Ref. 53) found that plant developmental stage plays an important role in the timing of PTGS initiation.

Experiments demonstrating that plant developmental stage determines PTGS initiation suggest that any environmental factors influencing plant growth would also affect the amount of time before RNA and protein production is effectively suppressed. At least one experiment has looked more directly at the influence of environmental factors on PTGS. Szittya *et al.* (Ref. 54) demonstrated that cold temperatures inhibited transgene-induced RNA silencing leading to increased levels of transgene mRNA, although they did not report on the level of transgenic protein.

In addition to temporal changes in protein production that may be influenced by varying environmental conditions, PTGS may also be associated with variation in protein expression across different plant tissues. Plant lines expressing a nitrate reductase transgene were found to display PTGS in leaves and stem tissue but not in shoot apical or axillary meristems (Ref. 52). As in other experiments (Ref. 51), transgene protein was not detectable and transgene mRNA levels were significantly reduced in plant tissue displaying PTGS. However, plant tissue in which gene silencing does not occur showed normal levels of transgene mRNA, and transgenic protein was produced.

It has been shown that PTGS can be suppressed by viruses that encode certain suppressor proteins leading to loss of the virus-resistant phenotype conferred by a PVCP-PIP. For example, Savenkov and Valkonen (Ref. 55) showed that resistance to Potato virus A (PVA) in *Nicotiana benthiana* could be overcome when plants were challenged with Potato virus Y (PVY). Although levels of transgene mRNA in healthy transgenic plants were extremely low or below the detection limit, transgene mRNA was readily detectable in PVY-infected plants where suppression of gene silencing had apparently occurred. The study did not report whether PVC-protein was produced from the transgene mRNA.

The 2005 SAP was asked to comment on issues associated with protein production in the case of plants containing a PVCP-PIP that confers resistance through an RNA-mediated mechanism. The Panel responded that ''[g]iven the wide variety of conditions that can modulate the transition from PTGS to no PTGS for non-[inverted repeat (IR)] transgenes. . .it is likely that a non-IR transgene insertion that retains an initiation codon for protein synthesis will make at least a low level of protein in at least some plant tissues over the course of its development, especially in the field where there is exposure to environmental extremes and virus infections. Thus, these PVCP-PIP plants may accumulate virus-derived mRNA and proteins in these situations'' (Ref. 15). EPA notes that the Panel further concluded that ''[b]ecause of low levels of accumulation and sequence identity to the natural viral pathotypes. . .these PVCP-PIPs pose similarly low risks'' as PVCP-PIPs that produce no protein (Ref. 15). However, any PVC-protein residue in food that is not covered by a tolerance or tolerance exemption would constitute an adulterant of the food supply irrespective of the protein's safety or the level at which it is detected.

The above considerations suggest that many factors should be considered in making a determination of whether residues of a PVC-protein will be present in food derived from a crop containing a PVCP-PIP. Due to the serious consequences of having an unapproved residue in the food supply (as discussed earlier in this unit), EPA strongly recommends that developers consult with the Agency before determining that no tolerance or tolerance exemption for the PVC-protein

would be necessary based solely on the premise that no residues of the protein are anticipated to be present. EPA expects that the Agency would conclude no PVC-protein tolerance exemption would be necessary for insertion events where the transgene either lacks an initiation codon for protein synthesis or is inserted in an inverted-repeat orientation, provided that evidence is given to the Agency to verify the characteristics of the insertion event. For such constructs, the 2005 SAP indicated the PVCP-PIP ''could be safely determined to have no [PVC-protein] expression regardless of plant tissue, developmental stage, environmental conditions, or exposure to virally-encoded suppressors of PTGS'' (Ref. 15).

For all other types of PVCP-PIP insertion events, EPA is considering several approaches under FFDCA for PVC-proteins that are not readily detectable, but which the SAP indicated would likely be produced under some circumstances (Ref. 15), some of which might result in the PVC-protein being in food. EPA does not currently have a preferred approach and presents several options to promote full consideration of the issues. These options are not necessarily mutually exclusive, and the approach pursued may vary depending on the characteristics of the PVCP-PIP under consideration. The discussion below relates only to proteins that EPA review would determine to be minimally modified, i.e., proteins that are similar, but not identical to natural plant virus coat proteins. Virtually unmodified PVC-proteins would be covered under the proposed tolerance exemption without any Agency action. The discussion is not relevant to proteins that would not be able to qualify under this proposal as either virtually unmodified or minimally modified because the proposed tolerance exemption would not cover such proteins regardless of how EPA implements the exemption.

Under one approach, when no PVC-protein is detected during product development, EPA would *not* issue a determination of whether the PVC-protein is minimally modified (and therefore falls under this proposed tolerance exemption). Section 408 of FFDCA does not require a tolerance or tolerance exemption for foods that do not bear any residues, and such an approach would be consistent with current EPA practice regarding chemical pesticide residues in that tolerance determinations are not generally issued for substances when residue studies demonstrate that detectable residues will not be present in food. However, if food is subsequently found bearing residues of the PVC-protein, that food would be adulterated and subject to seizure unless and until EPA could make a determination that the PVC-protein is minimally modified and is therefore covered by this proposed tolerance exemption.

Any adulterant in the food supply would likely cause public concern and great expense—whether or not the PVC-protein were subsequently determined to be safe. The Agency also notes that these costs are not necessarily borne by the product developer, but rather may disproportionately affect farmers and/or food producers because any adulterated food would be subject to seizure or recall. The Agency is considering this approach under the assumption that the absence of detectable protein using rigorous testing could give reasonable assurance that PVC-protein residues would not be found in food and therefore a tolerance determination would be unnecessary to prevent adulteration of the food supply. EPA would expect developers to provide the Agency with data acquired during product development that demonstrates no PVC-protein residues in food would be reasonably anticipated during the commercial life of the PVCP-PIP. For example, such data could be obtained by testing for protein and/or mRNA production in all plant tissues and all developmental stages that are harvested for food production under a variety of circumstances and environmental conditions representative of those that the plant may experience during its commercial cultivation. Challenge with a known PTGS suppressor protein introduced by a replicating virus vector, genetic crosses, or agro-infiltration (Ref. 56) may also in some cases be a sufficient and less burdensome technique to show that no PVC-protein is able to be translated from the PVCP-PIP. The potential to elicit protein production from silenced transgenes has been shown by studies investigating whether particular proteins are able to suppress such silencing (Ref. 56). The 2005 SAP discussed such a technique, indicating that ''[t]o determine if PTGS-based PVCP-PIP plants have the potential to produce proteins, the most effective test is to use viral suppression of PTGS. In this type of assay, the PVCP-PIP plants are infected with viruses from the potyvirus, cucumovirus, and tombusvirus genera. These viruses encode different classes of PTGS suppressor proteins. . . Protein and RNA are then extracted from the infected plant tissue and assayed for the presence of the PVCP-PIP accumulated full-length RNA and protein. Standard tests for protein detection are ELISA and immunoblot ('Western' blot) analyses with specific antibodies. Triplicate experiments should be sufficient to determine that the results of these tests are reproducible'' (Ref. 15). Given that FFDCA does not require a developer to demonstrate that no tolerance exemption is necessary, EPA would require such testing as a condition of either registering or exempting the PVCP-PIP under FIFRA.

If the developer detects a PVC-protein during the course of investigating potential PVC-protein production, e.g., through challenge with a suppressor protein, this protein would only be covered under the proposed categorical tolerance exemption, i.e., without any Agency action, if the protein falls within the definition of a virtually unmodified PVC-protein. Therefore, unless the protein is virtually unmodified from a natural plant virus coat protein, EPA would expect a developer to provide the Agency with information for a determination of whether the PVC-protein qualifies as minimally modified and meets the proposed conditional tolerance exemption. (See Unit IV.E.2. for a discussion of the factors EPA intends to consider in making this determination.)

When possible, EPA would expect to see biochemical characterization of the PVC-protein. However, EPA recognizes that such characterization may be difficult or even impossible in some cases. For example, when only very low levels of protein are produced, it may be difficult to obtain sufficient amounts of protein for biochemical characterization. In addition, EPA recognizes the cost and burden of producing sufficient protein for such characterization may not be warranted for PVC-proteins given that an evaluation based on the construct sequence alone could consider most of the issues EPA intends to evaluate when determining whether a PVC-protein is minimally modified (see Unit IV.E.2.).

EPA is therefore also considering a second approach to addressing PVC-proteins that are not detected during product development but whose presence as residues in food cannot be ruled out for the commercial life of the PVCP-PIP. Under this approach, EPA would evaluate the PVC-protein to determine whether it qualifies as minimally modified from a natural plant virus coat protein and is thus eligible for this proposed tolerance exemption based only on its amino acid sequence as deduced from the sequence of the inserted gene. EPA notes the advice of the 2005 SAP that ''[i]t is critical to evaluate the protein as expressed in the

host, including factors such as post-translational modifications'' (Ref. 15). Nevertheless, EPA considers evaluating the protein as expressed in the host to be less important for minimally modified PVC-proteins than for many other types of proteins. A PVC-protein would not be expected to have significantly different post-translational modifications than a plant virus coat protein produced in a virus-infected plant. Because plant viruses replicate in plant cells as part of their normal life cycle, any post-translational modifications are expected to be the same for a PVC-protein expressed from a plant transgene as for a plant virus coat protein expressed from a viral genome in a virus-infected plant.

As a third alternative, EPA is considering whether the Agency could expand this proposed tolerance exemption to cover all PVC-proteins that would be produced from constructs where resistance is demonstrated to EPA to be mediated through PTGS, e.g., those that confer virus resistance in the absence of detectable protein production for at least some period of time. The rationale for this alternative would be, as indicated by the 2005 SAP, that ''PTGS-based virus resistance requires greater than 90% RNA sequence homology between the PVCP-PIP transgene and the target virus, indicating that the viral mRNA and protein produced in PVCP-PIP plants will be nearly identical to the viral pathotype that occurs in the United States'' (Ref. 15). To implement this alternative, the Agency would have to be able to conclude, without any case-by-case examination, that any PVC-protein produced from a PVCP-PIP that mediates resistance through PTGS would be safe. Even if a PVC-protein were detected before product deployment, such a protein would not need any evaluation by the Agency in order to be covered by this tolerance exemption. The rationale for this approach would be that any such PVC-protein would meet the conditions of a minimally modified protein (as discussed in Unit IV.E.2.) given the necessity for transgene transcript sequence similarity to natural plant virus coat protein sequences in order for PTGS to effectively function. Although EPA does not believe it could identify *a priori* which modifications would be within the range of natural variation for the protein, under this rationale the induction of PTGS would be an *a priori* indicator that such a PVC-protein is within the range of natural variation of the protein. The 2005 SAP suggested that all PTGS-based PVCP-PIPs would ''pose similarly low risks'' as those that would have no protein expression under any circumstances (Ref. 15), giving scientific support for this option. However, the Agency notes that this advice is not entirely consistent with advice regarding PVC-protein safety received by the Panel. For one, both the 2004 and 2005 SAPs were unable to endorse a tolerance exemption for PVC-proteins other than those that are virtually unmodified from a natural plant virus coat protein unless the Agency performed a case-by-case review of some nature. PVC-proteins could be encoded for by a nucleic acid sequence that meets the 90% similarity required for PTGS to function but fail to be virtually unmodified from a natural virus coat protein (see Unit IV.E.1.). Moreover, the 2005 SAP recommended that ''[d]etermining whether PVC-proteins containing terminal deletions, or any other modifications, are within the range of natural variation would require the development of a database of the natural variation and truncated forms of PVC-proteins that occur naturally'' (Ref. 15). While PTGS requires a relatively high sequence similarity with natural virus coat proteins to function, only a portion of the coat protein gene is necessary, suggesting that many truncated proteins would be encompassed in this exemption without any review of whether they occur naturally. (See, however, EPA's discussion of whether truncated proteins could be determined to be exempt without Agency review in Unit IV.E.2.) The 2005 SAP also suggested that a low level of protein expression would indicate low risk, but prior SAPs and other scientific experts have been unable to establish a threshold below which the level of protein would not present concerns with respect to food allergenicity (Refs. 57 and 58).

V. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this proposed action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

EPA's risk assessment was based primarily on an analysis of human experiences with the breeding and cultivation of agricultural plants as well as food preparation and consumption. EPA combined human experience in consuming food containing coat proteins from viruses that naturally infect plants with knowledge of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry, and plant breeding to evaluate the potential risks of the residues of PVC-proteins qualifying for this proposed exemption.

EPA considered the nature of any toxic effects that might be caused by residues of PVC-proteins proposed for exemption. As mentioned above, coat proteins from plant viruses that naturally infect plants are widespread in foods (Refs. 6, 7, and 10) and are not associated with toxic or pathogenic effects in humans or vertebrates (Refs. 18 and 19). Residues of PVC-proteins qualifying for this proposed exemption are virtually unmodified or minimally modified from other coat proteins from viruses that naturally infect food plants and that have been safely consumed for hundreds if not thousands of years. Given this long history of safe use and the fact that toxicity is an unusual property among proteins in general (Ref. 59), consumption of food containing residues of PVC-proteins qualifying for this proposed exemption is not expected to present a toxic effect on humans or animals.

EPA considered the available information on the various dietary consumption patterns of consumers and major identifiable consumer subgroups as it pertains to residues of PVC-proteins in food. Plant virus coat proteins are, and always have been, widespread in all food from crop plants since most plants are susceptible to infection by one or more viruses. Thus, all consumers and all major identifiable consumer subgroups are, and have been, exposed to plant virus coat proteins. Implementation of this proposed exemption is not expected to alter the current consumption patterns of plant virus coat proteins except perhaps to reduce exposure through a decrease in virus-infected plants. Therefore, EPA does not expect any special sensitivities to arise due to the consumption of residues of PVC-proteins that are proposed to be exempted.

VI. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA considered the available information on the likely aggregate exposure level of consumers to PVC-proteins qualifying for this proposed exemption and to other related substances, including exposures to plant virus coat proteins occurring through natural processes such as viral infection of a food plant. This analysis included a consideration of exposures from dietary sources as well as from other non-occupational sources.

The PVC-proteins qualifying for this proposed exemption and plant virus coat proteins that occur naturally are both produced in living plants and are subject to the natural processes of degradation and decay that all biological materials undergo. They are broken down by enzymatic processes of living organisms into constituent parts that are used as building blocks for other biological substances (Ref. 60). Because of their biodegradable nature, neither PVC-proteins nor naturally occurring plant virus coat proteins bioaccumulate (i.e., build up in tissues because the body is unable to either break the substance down or eliminate it) or biomagnify (i.e., progressively build up in successive trophic levels because it bioaccumulates in the bodies of organisms lower in the food chain). Humans ingesting naturally occurring plant virus coat proteins and residues of PVC-proteins qualifying for this proposed exemption in food are likely to quickly degrade them and use their constituent elements as nutrients.

Because of these characteristics, there is limited potential for exposures to PVC-proteins qualifying for this proposed exemption beyond direct physical exposure to a plant. In most cases, the predominant exposure route will be dietary. In general, EPA anticipates that dietary exposure to PVC-proteins qualifying for this proposed exemption through human and animal consumption of plants expressing PVC-proteins will be similar to, or less than the amounts of plant virus coat proteins currently consumed through food plants that are infected naturally with viruses (see Unit IV.C.1.). Exposure through other routes is unlikely because the substances are in the plant tissue and thus are found either within the plant or in close proximity to the plant. EPA expects non-dietary exposure (i.e., non-food oral, dermal, and inhalation) in non–occupational settings to be negligible.

A. Dietary Exposure

EPA considered the consequences of dietary exposure to PVC-proteins that are the subject of this proposed exemption. A large base of experience exists, including information on human dietary exposure, for foods that contain coat proteins from viruses that naturally infect plants. As plant virus coat proteins are ubiquitous in food, EPA concluded that all humans are exposed to plant virus coat proteins throughout their lives as part of their diet. Neither naturally occurring plant virus coat proteins nor the PVC-proteins qualifying for this exemption are toxic, and there is no evidence that consumption in food of residues of PVC-proteins qualifying for this proposed exemption would lead to any harm.

1. *Food*. As mentioned in Unit IV.C.1., the Agency has concluded that dietary exposures to PVC-proteins qualifying for this proposed exemption will be similar to or less than the amounts of plant virus coat proteins currently found and consumed in food plants that have been naturally infected by viruses. Even if there were notable exposure to PVC-proteins, there is no evidence that PVC-proteins are toxic to humans. Moreover, the Agency is not aware of any coat protein from a virus that naturally infects plants that has been identified as a food allergen for humans. The residues that are proposed to be exempted by this **Federal Register** document would not differ substantially from residues of naturally occurring plant virus coat proteins.

2. *Drinking water exposure*. EPA also evaluated potential non–occupational exposures in drinking water. Residues of PVC-proteins that qualify for this proposed exemption are produced inside the plant itself. When the plant dies or a part is removed from the plant, microorganisms colonizing the tissue immediately begin to degrade it using the components of the plant tissue (including residues of PVC-proteins) as building blocks for making their own cellular components or for fueling their own metabolisms. PVC-proteins and naturally occurring plant virus coat proteins are subject to the same processes of biodegradation and decay that all biological materials undergo and are not known to either bioaccumulate or biomagnify (Ref. 60). Even if they were to reach surface waters (e.g., through plant parts or pollen falling into bodies of water), they are unlikely to present anything other than a very negligible exposure in drinking water drawn either from surface water or ground water sources due to biodegradation of these residues.

B. Other Non-Occupational Exposure

Residential exposure to PVC-proteins qualifying for this proposed exemption would be limited. Residential exposure could occur through use of PVCP-PIPs in ornamental plants or in plants grown in home gardens. Such exposure to PVC-proteins is expected to be negligible on a per-person basis compared to exposure to PVC-proteins and natural plant virus coat proteins in the diet. Furthermore, PVC-proteins qualifying for this exemption would not be toxic, and there is no evidence that exposure to such PVC-proteins would lead to any harm.

1. *Dermal exposure*. Residues of PVC-proteins qualifying for this proposed exemption may be present in sap or other plant exudates and thus may present some limited opportunity for dermal exposure to persons coming physically into contact with the plant or raw agricultural food from the plant. Individuals preparing meals are those most likely to experience dermal contact with the residues on a non-occupational basis. As noted by the 2005 SAP, PVC-proteins' ''natural exposure route may be via oral ingestion. However, genetically modified expression of PVCP-PIPs would lead to the presence of [PVC-proteins] in other plant compartments such as pollen grains which lead to other sites of exposure including respiratory and cutaneous surfaces'' (Ref. 15). However, the potential amount involved in such exposure on a per person basis is likely to be negligible in comparison to potential exposure through the dietary route to PVC-proteins and natural plant virus coat proteins (Ref. 61). Moreover, PVC-proteins qualifying for this proposed exemption or naturally occurring plant virus coat proteins that occur in food are unlikely to cross the barrier provided by the skin (Ref. 62).

2. *Inhalation exposure*. Pollen could potentially contain residues of PVC-proteins qualifying for this proposed exemption. Individuals (e.g., those visiting, living, or working near enough to farms, nurseries, or other plant-growing areas to be exposed to wind-blown pollen) may be exposed to the pollen through inhalation. On a per person basis, the potential amount of pollen involved in these exposures is likely to be negligible in comparison to potential exposure through the dietary route (Ref. 61). Some members of the 2005 SAP indicated that ''[i]ntroduction of new proteins to pollens and other plant materials may have the potential to cause problems, and consideration by the Agency is warranted'' (Ref. 15). As the Panel explained, ''While plant viruses systemically infect plant tissues, there is tissue specific regionalization of viruses. Therefore [plant virus coat proteins] would be restricted within certain compartments. Transgenic expression of some PVC-PIPs would

promote [PVC-protein] expression in different plant tissues relative to what would naturally occur (i.e., all cells). This could lead to heightened levels of [PVC-proteins] in certain tissues (i.e., pollen grains) and the effects (specifically to allergenicity) are not yet known. This has implications for non-dietary exposure of plant proteins. In some instances, [plant virus coat protein's] natural exposure route may be via oral ingestion. However, genetically modified expression of PVCP-PIPs would lead to the presence of [PVC-proteins] in other plant compartments such as pollen grains which lead to other sites of exposure including respiratory and cutaneous surfaces'' (Ref. 15). However, other Panel members felt that ''unless there is evidence that PCVP-PIPs are expressed on the surface of pollen grains in a manner different from expression in wild-type plants, the risk of increased allergy from exposure to pollen is non-existent'' (Ref. 15). The Agency also notes that in order for expression of a PVC-protein to be a concern, the protein would have to be expressed on the surface of the pollen grain, it would have to actually be an antigenic protein, and it would have to elicit an allergic response through secondary exposure. The Agency considers that this sequence of events is very unlikely to occur, in part because no plant virus coat proteins have been identified as being allergenic, and PVC-proteins qualifying for this exemption are virtually unmodified or minimally modified from natural plant virus coat proteins. Therefore, it is unlikely that inhalation exposure to PVC-proteins in pollen would result in adverse effects.

VII. Cumulative Effects

EPA examined the available information on residues of PVC-proteins qualifying for this proposed exemption for cumulative effects with other substances, including natural plant virus coat proteins. Plant virus coat proteins are nontoxic proteins that are widespread in food from plants. They have not been associated with toxic effects to animals or humans (see Unit IV.C.3.). EPA is therefore not aware of any other substances that could have a common mechanism of human toxicity with residues of PVC-proteins qualifying for this exemption and cannot identify any cumulative effects of such residues with any other substances.

VIII. Safety Factor for Infants and Children

A. In General

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the information base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

B. Prenatal and Postnatal Sensitivity

EPA considered available information on the dietary consumption patterns of infants and children as it pertains to residues in food of PVC-proteins qualifying for this proposed exemption. The range of foods consumed by infants and children is in general more limited than the range of foods consumed by adults. Most newborns rely on breast milk or formula-based products for nutrition, although some infants are fed soy-based products. Infants may begin as early as 4 months of age to consume solid foods that are based on foods consumed by the general adult population albeit in different proportions and with processing to facilitate swallowing. As infants and children mature, more and more of the foods normally consumed by adults become part of their diets, and the relative proportions of the different types of food consumed change to more closely resemble an adult diet. Because plant viruses are ubiquitous in plant foods, EPA concluded that infants and children are exposed to plant virus coat proteins from the time they begin to eat food of plant origin. As the diets of humans change from infancy through childhood and into adulthood, there is some possibility that the amount of plant virus coat proteins being consumed may change, with those consuming the greatest amounts of food of plant origin most likely exposed to the most plant virus coat protein. However, there is no evidence that such changes are likely to result in disproportionately high consumption of foods containing plant virus coat proteins among infants and children in comparison to the general population. Furthermore, PVC-proteins qualifying for this proposed exemption are not toxic, and there is no evidence that any amount of exposure to such PVC-proteins in food would lead to any harm.

EPA considered available information on the potential for special susceptibility of infants and children, including prenatal and postnatal toxicity, to residues of PVC-proteins qualifying for this proposed exemption. PVC-proteins in food are not toxic. There is no scientific evidence that residues of such PVC-proteins in food would have a different effect on infants and children than adults due to neurological differences between infants, children, and adults.

The Agency's consideration of cumulative effects of the residues of PVC-proteins qualifying for this proposed exemption on the general population also included consideration of effects for infants and children. Neither naturally occurring plant virus coat proteins nor PVC-proteins qualifying for this proposed exemption are toxic when consumed as part of the diet, and EPA is not aware of any substances that might have a common mechanism of toxicity with these PVC-proteins. There is no scientific evidence indicating any potential for adverse effects on infants and children due to cumulative exposure to residues of such PVC-proteins. EPA concludes that there is no evidence of a common mechanism of toxicity between PVC-proteins qualifying for this proposed exemption and any other substances, and therefore, no cumulative effects of these PVC-proteins would reasonably be anticipated.

C. Conclusion

There is a complete toxicity base of information for PVC-proteins that are the subject of this proposed exemption, and exposure data are estimated based on data that reasonably account for potential exposures. For residues of PVC-proteins qualifying for this proposed exemption, EPA has determined that a tenfold margin of safety is not necessary to protect infants and children. As noted in Unit IV.C., EPA based its assessment of exposure and toxicity on the long history of safe human and animal consumption of food containing plant virus coat proteins. EPA also relied upon information from the disciplines of plant genetics, plant physiology, plant virology, microbial ecology, ecology, biochemistry, molecular biology, and plant breeding. Based on all of this information, EPA concludes that PVC-proteins qualifying for this proposed exemption in food are not toxic and may be safely consumed, including by infants and children. There is no evidence that exposure to such

PVC-proteins in food, including changes in exposure because of changes in the relative proportions of the different types of food consumed from infancy through childhood and into adulthood, leads to any harm. Thus, on the basis of valid, complete, and reliable information, EPA has concluded that residues in food of PVC-proteins qualifying for this proposed exemption are safe for infants and children and that an additional margin of safety need not be applied.

IX. Other Considerations

A. Endocrine Disruptors

Based on available information that plant virus coat proteins are ubiquitous in foods and have no known adverse effects when consumed as part of the diet (see Unit IV.C.), EPA does not expect residues of PVC-proteins qualifying for this proposed exemption to cause estrogenic or other endocrine effects. In the May 16, 1997 supplemental document, EPA specifically requested comment on PVC-proteins causing estrogenic effects. No information was received indicating that either naturally occurring plant virus coat proteins or PVC-proteins that qualify for this proposed exemption might cause estrogenic or other endocrine effects. If EPA becomes aware of a potential for estrogenic or endocrine effects from exposure to residues of such PVC-proteins, the Agency will reexamine this proposed tolerance exemption in light of that information.

B. Analytical Method(s)

EPA has concluded that even though methodology exists to detect residues of PVC-proteins (Refs. 63, 64, and 65), there is no need to employ a practical method for detecting and measuring the level of residues of PVC-proteins qualifying for this exemption. There is no reason to believe that the residues of PVC-proteins proposed to be exempted in this **Federal Register** document would behave any differently than naturally occurring plant virus coat proteins in food. There is a reasonable certainty that no harm will result from exposure to any amount of residues in food of such PVC-proteins. Because these residues may be present in food at any level without causing harm, EPA has concluded that an analytical method is not required for detecting and measuring the level of residues of these PVC-proteins in food. EPA consulted with the Department of Health and Human Services (HHS) in making this determination.

C. Codex Maximum Residue Level

There are no Codex maximum residue levels established for PVC-proteins.

X. Preliminary Determination of Safety for U.S. Population, Infants, and Children

Based on the information discussed in this document and that discussed in the 1994 **Federal Register** documents, the supplemental documents, and the associated record as described in Unit XII.B., EPA preliminarily concludes that there is a reasonable certainty that no harm will result to the U.S. population, infants, and children from aggregate exposures to residues of PVC-proteins that qualify for this proposed exemption. Many years of experience with growing, preparing, and consuming food from plants containing plant virus coat proteins and information generated through years of study of the food supply (Refs. 6, 7, 8, 9, 10, and 66) indicate that adverse effects due to aggregate exposure to PVC-proteins qualifying for this proposed exemption through dietary, non-food oral, dermal, and inhalation routes are highly unlikely.

XI. Request for Comment

EPA requests comment on whether this proposed tolerance exemption identifies those PVC-proteins that are unlikely to result in new dietary exposures. When commenting, please use the terminology conventions adopted in this document, i.e., use ''plant virus coat protein'' when referring to the protein produced naturally from a plant virus, and use ''PVC-protein'' when referring to the protein component of a PVCP-PIP. The Agency requests comment on the following specific issues:

1. EPA requests comment on the options discussed in Unit IV.E.1. for defining virtually unmodified. Under the Agency's proposed rule, virtually unmodified proteins would be exempt from the requirement of a tolerance without Agency review. Under one option, virtually unmodified would be defined as having or coding for an amino acid sequence that is identical to an entire coat protein of a naturally occurring plant virus; except for the addition of one or two amino acids at the N- and/or C-terminus other than cysteine, asparagine, serine, and threonine and/or the deletion of one or two amino acids at the N- and/or C-terminus. However, the Agency is considering removing the limitations on which amino acids may be added and on the number of amino acids that may be truncated from either end of a PVC-protein.

2. In addition to the types of changes discussed in the paragraph above, EPA requests comment on whether any other class of potential PVC-protein modifications (e.g., a particular number of amino acid substitutions) would always be expected to produce a PVC-protein as safe as an unmodified plant virus coat protein such that the protein would not warrant a case-by-case Agency review for a tolerance exemption. The Agency also requests that commenters indicate whether the number and combination of such modifications has any relevance to the product's safety. In October 2004, the FIFRA SAP was asked to consider the degree and ways a plant virus coat protein gene might be modified while still retaining scientific support for the idea that humans have consumed the products of such genes for generations and that such products therefore present no new dietary exposures (Ref. 14). They responded that ''[t]here was no clear consensus on how much change would be necessary to invalidate this assumption, although there was general agreement that the appropriate comparison is to the range of natural variation in the virus population.'' This question was also addressed by the 2005 SAP which concurred that ''it is extremely difficult to identify modifications that would be expected to be 'within the range of natural variation for all virus families'. . . Given the possible range of natural variations for PVC proteins, it would be appropriate to assess whether specific modifications are within natural variation limits of the PVC protein on a case-by-case basis'' (Ref. 15). Commenters should specifically address this advice when formulating comments.

3. EPA requests comment on whether there would be any safety issues associated with exposure to PVC-proteins if the virus used to create the PVCP-PIP does not naturally infect the particular plant species into which the PVCP-PIP is inserted. A PVC-protein may be expressed in a food plant that the virus does not naturally infect when heterologous resistance to a particular virus is conferred through a different virus' coat protein gene (e.g., Ref. 45). Such PVC-proteins could be safely exempted from tolerance requirements if these proteins are reasonably expected to be part of the current diet, as discussed in Unit IV.E.1. In light of the uncertainty surrounding the SAP's remarks concerning this issue (see Unit IV.E.1.), EPA requests comment on whether there would be any safety issues associated with exposure to*the*

PVC-proteins themselves if the virus used to create a PVCP-PIP does not naturally infect the particular plant species into which the PVCP-PIP is inserted.

4. EPA requests comment on whether the Agency should consider the level of PVC-protein expression in determining whether a PVC-protein is virtually unmodified or minimally modified and thus exempt from tolerance requirements. EPA concurs with the 2005 SAP that ''exposure level is an important component of an allergenicity risk assessment'' (Ref. 15). However, it can be argued that PVC-proteins that are virtually unmodified or minimally modified when compared to natural plant viral coat proteins are of sufficiently low hazard that the potential risk does not rise to the level warranting regulation, even in the rare case that exposure to a PVC-protein might be greater than the exposure to the corresponding natural plant virus coat protein. Although EPA's review of PVC-proteins to determine if they are minimally modified could allow the Agency to consider PVC-protein expression level relative to natural levels of plant virus coat proteins, the Agency is unsure how this factor could be readily incorporated into the criteria for a developer-determined tolerance exemption; EPA anticipates needing to consider the appropriateness of data designed to address these questions on a case-by-case basis. Therefore, if protein expression level is considered a necessary factor in evaluating whether to exempt a virtually unmodified PVC-protein from tolerance requirements, EPA seeks comment on how such considerations could be articulated in a clear, unambiguous criterion.

5. EPA requests comment on the Agency's options for how to view a PVC-protein that would not meet the definition of virtually unmodified and is not detected during product development if the construct suggests that its production is likely to occur in at least some plant tissue at some point in time (see Unit IV.F.). Specifically, EPA requests comment on the relative costs and benefits of allowing a PVCP-PIP that does not produce detectable PVC-protein residues in food during product development to be sold or distributed without a PVC-protein tolerance exemption in place. EPA is particularly interested in information about the likelihood that protein would fail to be detected during product development but subsequently be detected in food. The Agency is also interested in comments on conditions under which protein detection protocols could be conducted to provide adequate assurance that such events would not occur, e.g., any key environmental parameters that should be varied during testing.

EPA also requests comment on whether obtaining characterization data of a plant-produced PVC-protein for a tolerance review is scientifically feasible in all cases where the PVCP-PIP insertion event contains a translation initiation codon and is not present in an inverted repeat orientation. The Agency would like to know for any given crop how technically difficult it would be to attempt to induce protein production through challenge with a known PTGS suppressor protein, e.g., through introduction by a replicating virus vector, genetic crosses, or agro-infiltration (Ref. 56). In addition, EPA would like to know how likely it is that such techniques could yield sufficient quantities of PVC-protein for analysis (e.g., mass spectrometry or glycosylation analysis). The Agency would also be interested in hearing of additional techniques that could be employed to obtain plant-produced PVC-protein in cases where PTGS normally prevents accumulation of protein but is not expected to be consistently activated, thereby leading to PVC-protein production.

Regarding the second alternative presented for PVC-proteins associated with PTGS, EPA requests comment on the value of the additional information gained by analyzing an actual PVC-protein as produced in the plant where the inserted nucleotide sequence suggests it would be minimally modified from a natural plant virus coat protein, e.g., to consider potential post-translational modifications, relative to the reduced burden and cost of analyzing safety based on the deduced amino acid sequence from the insert alone.

Regarding the third alternative presented, EPA requests comment on the rationale that would be used to support expanding this tolerance exemption to cover all PVC-proteins produced by a PVCP-PIP that mediates resistance through PTGS, i.e., that any such protein would meet the conditions of a minimally modified protein as discussed in this document given the necessity for transgene transcript sequence similarity to natural plant virus coat protein sequences in order for PTGS to effectively function. In particular, EPA requests comment on how to reconcile this option with prior advice of the SAP (as discussed in Unit IV.F.).

6. EPA requests comment on whether PVC-proteins that the Agency has reviewed and has determined are minimally modified and therefore are exempt from the requirement of a tolerance under proposed § 174.477(b) should be listed in the CFR as is the current practice for individual tolerance exemptions associated with other types of PIPs. If so, EPA requests comment on whether the listing should indicate the specific modifications of the reviewed proteins, given that each determination would apply only to proteins with those modifications. EPA is aware that in the past, developers have found such listings to be useful for international trade reasons, as governments rely on EPA tolerances to support import decisions.

XII. References

A. Books, Articles, and Reports Used in Preparing this Proposed Rule

1. Callaway A., Giesman-Cookmeyer D., Gillock E.T., Sit T.L., Lommel S.A. The multifunctional capsid proteins of plant RNA viruses. *Annual Review of Phytopathology* 2001; 39:419-60.

2. Powell P.A., Sanders P.R., Tumer N., Fraley R.T., Beachy R.N. Protection against tobacco mosaic virus infection in transgenic plants requires accumulation of coat protein rather than coat protein RNA sequences. *Virology* 1990; 175:124-30.

3. Goldbach R., Bucher E., Prins M. Resistance mechanisms to plant viruses: an overview. *Virus Research* 2003; 92:207-12.

4. National Research Council. Genetically Modified Pest-Protected Plants: Science and Regulation. Washington, DC: National Academy Press, 2000.

5. Dewan C., Pearson M.N. Natural field infection of garlic by garlic yellow streak virus in the Pukekohe area of New Zealand and associated problems with the introduction of new garlic cultivars. *New Zealand Journal of Crop and Horticultural Science* 1995; 23:97-102.

6. McKinney H.H. Mosaic diseases in the Canary Islands, West Africa, and Gibraltar. *Journal of Agricultural Research* 1929; 39:557-78.

7. Provvidenti R., Gonsalves D. Occurrence of zucchini yellow mosaic virus in cucurbits from Connecticut, New York, Florida, and California. *Plant Disease* 1984; 68:443-6.

8. Palukaitis P. Virus-mediated genetic transfer in plants. In: Levin M, Strauss H. Risk Assessment in Genetic Engineering. New York: McGraw-Hill, 1991:140-62.

9. Jones L., Anderson E., Burnett G. The latent virus of potatoes. *Journal of Phytopathology* 1934; 7:93-115.

10. Beemster A.B.R., de Bokx J.A. Survey of properties and symptoms. In:

de Bokx J.A., van der Want J.P.H. Viruses of Potatoes and Seed Potato Production. Wageningen: Pudoc, 1987:84-93.

11. Fulton R. Practices and precautions in the use of cross protection for plant virus disease control. *Annual Review of Phytopathology* 1986; 24:67-81.

12. Zhang T., Breitbart M., Lee W.H., Run J-Q, Wei CL, Soh SWL et al. RNA viral community in human feces: prevalence of plant pathogenic viruses. *PLoS Biology* 2006; 4:e3.

13. FIFRA Scientific Advisory Panel (Subpanel on Plant Pesticides). Minutes of the December 18, 1992 Meeting on A Set of Scientific Issues Being Considered by the Agency in Connection with the Proposed Regulation of Plant Pesticides. 1992.

14. FIFRA Scientific Advisory Panel. Minutes of the October 13-15, 2004 Meeting on Issues Associated with Deployment of a Type of Plant-Incorporated Protectant (PIP), Specifically those Based on Plant Viral Coat Proteins (PVCP-PIPs). 2004.

15. FIFRA Scientific Advisory Panel. Minutes of the December 6-8, 2005 Meeting on Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule. 2005.

16. Quemada H. Food safety evaluation of a transgenic squash. OECD Workshop on Food: Provisionsal Proceedings of the Safety Evaluation. Paris: OECD, 1994:71-9.

17. Hull R. Matthews' Plant Virology, Fourth ed. San Diego: Academic Press, 2002.

18. Miller J. Biotech boosts natural bounty. *Today's Chemist at Work* 2000; 9:38-44.

19. Elbehri A. Biopharming and the Food System: Examining the Potential Benefits and Risks. *AgBioForum* 2005; 8:18-25.

20. Downs S.H., Marks G.B., Sporik R., Belosouva E.G., Car N.G., Peat J.K. Continued increase in the prevalence of asthma and atopy. *Archives of Disease in Childhood* 2001; 84:20-3.

21. von Mutius E., Weiland S.K., Fritzsch C., Duhme H., Keil U. Increasing prevalence of hay fever and atopy among children in Leipzig, East Germany. *Lancet* 1998; 351:862-6.

22. Heinrich J., Hoelscher B., Frye C., Meyer I., Wjst M., Wichmann H-E. Trends in prevalence of atopic diseases and allergic sensitization in children in Eastern Germany. *European Respiratory Journal* 2002; 19:1040-6.

23. Naraghi-Arani P., Daubert S., Rowhani A. Quasispecies nature of the genome of *Grapevine fanleaf virus. Journal of General Virology* 2001; 82:1791-5.

24. Schneider W.L., Roossinck M.J. Genetic diversity in RNA virus quasispecies is controlled by host-virus interactions. *Journal of Virology* 2001; 75:6566-71.

25. Kim T., Youn M.Y., Min B.E., Choi S.H., Kim M., Ryu KH. Molecular analysis of quasispecies of Kyuri green mottle mosaic virus. *Virus Research* 2005; 110:161-7.

26. Roossinck M.J. Mechanisms of plant virus evolution. *Annual Review of Phytopathology* 1997; 35:191-209.

27. Zhou X., Liu Y., Calvert L., Munoz C., Otim-Nape G.W., Robinson DJ et al. Evidence that DNA-A of a geminivirus associated with severe cassava mosaic disease in Uganda has arisen by interspecific recombination.*Journal of General Virology* 1997; 78:2101-11.

28. Desbiez C., Lecoq H. The nucleotide sequence of *Watermelon mosaic virus (WMV, Potyvirus)* reveals interspecific recombination between two related potyviruses in the 5' part of the genome.*Archives of Virology* 2004; 149:1619-32.

29. Allison R.F., Janda M., Ahlquist P. Sequence of cowpea chlorotic mottle virus RNAs 2 and 3 and evidence of a recombination event during bromovirus evolution. *Virology* 1989; 172:321-30.

30. Chenault K.D., Melcher U. Phylogenetic relationships reveal recombination among isolates of cauliflower mosaic virus.*Journal of Molecular Evolution*. 1994; 39:496-505.

31. Gibbs M.J., Cooper J.I. A recombinational event in the history of luteoviruses probably induced by base-pairing between the genomes of two distinct viruses. *Virology* 1995; 206:1129-32.

32. Le Gall O.L., Lanneau M., Candresse T., Dunez J. The nucleotide sequence of the RNA-2 of an isolate of the English serotype of tomato black ring virus: RNA recombination in the history of nepoviruses. *Journal of General Virology*. 1995; 76:1279-83.

33. Masuta C., Ueda S., Suzuki M., Uyeda I. Evolution of a quadripartite hybrid virus by interspecific exchange and recombination between replicase components of two related tripartite RNA viruses. *Proceedings of the National Academy of Sciences*. 1998; 95:10487-92.

34. Pita J.S., Fondong V.N., Sangare A., Otim-Nape G.W., Ogwal S., Fauquet C.M. Recombination, pseudorecombination and synergism of geminiviruses are determinant keys to the epidemic of severe cassava mosaic disease in Uganda. *Journal of General Virology* 2001; 82:655-65.

35. Moonan F., Molina J., Mirkov T.E. Sugarcane yellow leaf virus: an emerging virus that has evolved by recombination between luteoviral and poleroviral ancestors. *Virology* 2000; 269:156-71.

36. Worobey M., Holmes E.C. Evolutionary aspects of recombination in RNA viruses. *Journal of General Virology* 1999; 80:2535-43.

37. García-Arenal F., Fraile A., Malpica J.M. Variability and genetic structure of plant virus populations. *Annual Review of Phytopathology* 2001; 39:157-86.

38. Rodrigues-Alvarado G., Kurath G., Dodds J.A. Heterogeneity in pepper isolates of cucumber mosaic virus. *Plant Disease* 1995; 79:450-5.

39. Fraile A., Malpica J.M., Aranda M.A., Rodriguez-Cerezo E., Garca-Arenal F. Genetic diversity in tobacco mild green mosaic tobamovirus infecting the wild plant *Nicotiana glauca. Virology* 1996; 223:148-55.

40. Brunt, A.A., Crabtree, K., Dallwitz, M.J., Gibb, A.J., Watson, L., and Zurcher, E. Plant Viruses Online: Descriptions and Lists from the VIDE Database Version: 20th August 1996. *http://image.fs.uidaho.edu/vide/*.

41. Kurganov B.I., Rafikova E.R., Dobrov E.N. Kinetics of thermal aggregation of tobacco mosaic virus coat protein. *Biochemistry (Moscow*) 2002; 67:525-33.

42. Liu H., Boulton M.I., Oparka K.J., Davies J.W. Interaction of the movement and coat proteins of Maize streak virus: implications for the transport of viral DNA. *Journal of General Virology* 2001; 82:35-44.

43. Sacher R., Ahlquist P. Effects of deletions in the N-terminal basic arm of brome mosaic virus coat protein on RNA packaging and systemic infection. *Journal of Virology* 1989; 63:4545-52.

44. FIFRA Scientific Advisory Panel. Report of the June 6-7, 2000 Meeting on Mammalian Toxicity Assessment Guidelines for Protein Plant Pesticides. 2000.

45. Dinant S., Blaise F., Kusiak C., Astier-Manifacier S., Albouy J. Heterologous resistance to potato virus Y in transgenic tobacco plants expressing the coat protein gene of lettuce mosaic potyvirus. *Phytopathology* 1993; 83:819-24.

46. Breiteneder H., Pettenburger K., Bito A., Valenta R., Kraft D., Rumpold H. et al. The gene coding for the major birch pollen allergen Betv1, is highly homologous to a pea disease resistance response gene. *The EMBO Journal* 1989; 8:1935-8.

47. Breiteneder H., Ebner C. Molecular and biochemical classification of plant-derived food

allergens. *The Journal of Allergy and Clinical Immunology* 2000; 106:27-36.

48. Breiteneder H., Radauer C. A classification of plant food allergens. *The Journal of Allergy and Clinical Immunology* 2004; 113:821-30.

49. Ebner C., Hoffmann-Sommergruber K., Breiteneder H. Plant food allergens homologous to pathogenesis-related proteins. *Allergy* 2001; 56:43-4.

50. Davis M., Ying Z. Development of papaya breeding lines with transgenic resistance to *Papaya ringspot virus*. *Plant Disease* 2004; 88:352-8.

51. Lindbo J.A., Silva-Rosales L., Proebsting W.B., Dougherty W.G. Induction of a highly specific antiviral state in transgenic plants: Implications for regulation of gene expression and virus resistance. *The Plant Cell* 1993; 5:1749-59.

52. Béclin C., Berthomé R., Palauqui J.C., Tepfer M., Vaucheret H. Infection of tobacco or Arabidopsis plants by CMV counteracts systemic post-transcriptional silencing of nonviral (trans)genes. *Virology* 1998; 252:313-7.

53. Pang S-Z, Jan F.J., Carney K., Stout J., Tricoli D.M., Quemada H. et al. Post-transcriptional transgene silencing and consequent tospovirus resistance in transgenic lettuce are affected by transgene dosage and plant development. *Plant Journal* 1996; 9:899-909.

54. Szittya G., Silhavy D., Molnár A., Havelda Z., Lovas A, Lakatos L. et al. Low temperature inhibits RNA silencing-mediated defence by the control of siRNA generation. *The EMBO Journal* 2003; 22:633-40.

55. Savenkov E.I., Valkonen J.P.T. Coat protein gene-mediated resistance to *Potato virus A* in transgenic plants is suppressed following infection with another potyvirus. *Journal of General Virology* 2001; 82:2275-8.

56. Li W.X., Ding S.W. Viral suppressors of RNA silencing. *Current Opinion in Biotechnology* 2001; 12:150-4.

57. FIFRA Scientific Advisory Panel. Minutes of the July 17-18, 2001 Meeting on A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Assessment of Additional Scientific Information Concerning StarLink™ Corn. 2001.

58. FIFRA Scientific Advisory Panel. Minutes of the November 28, 2000 Meeting on A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Assessment of Scientific Information Concerning StarLink™ Corn. 2000.

59. Pariza M., Johnson E. Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century. *Regulatory Toxicology and Pharmacology* 2001; 33:173-86.

60. Berg J., Tymoczko J., Stryer L., Clarke N. Biochemistry, 5th ed. New York: W. H. Freeman and Company, 2002.

61. Environmental Protection Agency. Issue Paper on Dermal and Inhalation Exposure to Plant Substances. 2000.

62. Guy R.H., Hadgraft J. Principles of skin permeability relevant to chemical exposure. In: Hobson DW. Dermal and Ocular Toxicology: Fundamentals and Methods. Boca Raton: CRC Press, 1991:221-46.

63. Huguenot C., van den Dobbelsteen G., de Haan P., Wagemakers C., Drost G., Osterhaus A. et al. Detection of tomato spotted wilt virus using monoclonal antibodies and riboprobes. *Archives of Virology* 1990; 110:47-62.

64. Rocha-Pena M., Lee R., Niblett C. Development of a dot-immunobinding assay for detection of citrus tristeza virus. *Journal of Virological Methods* 1991; 34:297-309.

65. Sukhacheva E., Novikov V., Plaksin D., Pavlova I., Ambrosova S. Highly sensitive immunoassays for detection of barley stripe mosaic virus and beet necrotic yellow vein virus. *Journal of Virological Methods* 1996; 56:199-207.

66. Hull R., Covey S.N., Dale P. Genetically modified plants and the 35S promoter: assessing the risks and enhancing the debate. *Microbial Ecology in Health and Disease* 2000; 12:1-5.

B. Additional Information

EPA has established an official record for this rulemaking. The official record includes all information considered by EPA in developing this proposed rule including documents specifically referenced in this action, any public comments received during an applicable comment period, and any other information related to this action, including any information claimed as CBI and any information received in any of the related dockets mentioned in this unit. This official record includes all information physically located in the dockets described in the following paragraphs, as well as any documents that are referenced in the documents in the dockets.

1. The docket identified by the docket control number OPP–300370 for the document entitled ''Proposed Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act'' (59 FR 60496, November 23, 1994) (FRL–4755–2).

2. The docket identified by the docket control number OPP–300369 for the document entitled ''Plant-Pesticides Subject to the Federal Insecticide, Fungicide and Rodenticide Act; Proposed Rule'' (59 FR 60519, November 23, 1994) (FRL–4755–3).

3. The docket identified by the docket control number OPP–300368 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act'' (59 FR 60535, November 23, 1994) (FRL–4758–8).

4. The docket identified by the docket control number OPP–300371 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants'' (59 FR 60542, November 23, 1994) (FRL–4755–5).

5. The docket identified by the docket control number OPP–300367 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants'' (59 FR 60545, November 23, 1994) (FRL–4755–4).

6. The docket identified by the docket control number OPP–300370A for the document entitled ''Plant-Pesticide Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Reopening of Comment Period'' (61 FR 37891, July 22, 1996) (FRL–5387–4).

7. The docket identified by the docket control number OPP–300368A for the document entitled ''Plant-Pesticides; Supplemental Notice of Proposed Rulemaking'' (62 FR 27132, May 16, 1997) (FRL–5717–2).

8. The docket identified by the docket control number OPP–300371A for the document entitled ''Plant-Pesticides; Nucleic Acids; Supplemental Notice of Proposed Rulemaking'' (62 FR 27142 May 16, 1997) (FRL–5716–7).

9. The docket identified by the docket control number OPP–300367A for the document entitled ''Plant-Pesticides; Viral Coat Proteins; Supplemental Notice of Proposed Rulemaking'' (62 FR 27149, May 16, 1997) (FRL–5716–6).

10. The docket identified by the docket control number OPP-300369A for the document entitled ''Plant-Pesticides, Supplemental Notice of Availability of Information'' (64 FR 19958, April 23, 1999) (FRL–6077–6).

11. The docket identified by the docket control number OPP-300368B for the document entitled ''Exemption From the Requirement of a Tolerance

Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding From Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37830, July 19, 2001) (FRL–6057–6).

12. The docket identified by the docket control number OPP–300371B for the document entitled ''Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37817, July 19, 2001) (FRL–6057–5).

13. The docket identified by the docket control number OPP–300369B for the document entitled ''Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (66 FR 37772, July 19, 2001) (FRL–6057–7).

14. The docket identified by the docket control number OPP-300370B for the document entitled ''Plant-Incorporated Protectants (Formerly Plant-Pesticides), Supplemental Proposal'' (66 FR 37855, July 19, 2001) (FRL–6760–4).

15. The docket identified by the docket ID number EPA–HQ–OPP–2006–0642 for the companion document entitled ''Exemption under the Federal Insecticide, Fungicide, and Rodenticide Act for Certain Plant-Incorporated Protectants Derived from Plant Viral Coat Protein Gene(s) (PVCP-PIPs)'' (FRL–8100–7) published elsewhere in this issue of the **Federal Register**.

16. The docket identified by the docket ID number EPA–HQ–OPP–2006–0643 for this document (FRL–8100–5).

Also included in the complete official public record are:

- Public comments submitted in response to the proposals and supplemental documents cited in the above paragraphs.
- Reports of all meetings of the Biotechnology Science Advisory Committee and the FIFRA Scientific Advisory Panel pertaining to the development of this final rule.
- Support documents and reports.
- Records of all communications between EPA personnel and persons outside EPA pertaining to the proposed rule. (This does not include any inter- and intra-agency memoranda, unless specifically noted in the indices of the dockets).
- Published literature that is cited in this document.

XIII. Statutory and Executive Order Reviews

This proposed rule would establish an exemption from therequirement of a tolerance under section 408 of FFDCA. The Officeof Management and Budget (OMB) has exempted these types of actionsfrom review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866, this proposal is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This proposed rule does not contain any new information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a general matter, that there is no adverse economic impact associated with tolerance actions. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950). Since this proposed rule will not have an adverse economic impact, EPA hereby certifies under section 605(b) of the RFA that this action will not have a significant adverse economic impact on a substantial number of small entities. Tolerance actions, such as this proposed exemption, directly regulates growers, food processors, food handlers and food retailers, not States or tribes. Tolerance actions do not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, this rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

As with all aspects of its proposal, EPA invites your comments on these determinations.

List of Subjects in 40 CFR Part 174

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

Dated: April 9, 2007.

Stephen L. Johnson,

Administrator.

Therefore, it is proposed that 40 CFR part 174 be amended as follows:

PART 174—[AMENDED]

1. The authority citation for part 174 would continue to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

2. By adding § 174.477 to read as follows:

§ 174.477 Plant virus coat protein portion of a PVCP-PIP (PVC-protein); exemption from the requirement of a tolerance.

(a) Residues of a PVC-protein from a PVCP-PIP are exempt from the requirement of a tolerance if the encoded PVC-protein is virtually unmodified when compared to an entire unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part.

(b) When the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance has been modified (e.g., through internal deletions, addition of nucleotides from other virus coat protein genes, or substitutions leading to amino acid changes), residues of the PVC-protein may be exempt if the Agency determines, after review, that the encoded PVC-protein has been

minimally modified when compared to an entire unmodified coat protein from a virus that naturally infects plants that humans consume *in toto* or in part.

(c) Agency determinations made under paragraph (b) of this section may be made in response to a petition submitted in accordance with the provisions of 40 CFR part 177 or on the Agency's own initiative.

[FR Doc. E7–7296 Filed 4–17–07; 8:45 am]

BILLING CODE 6560–50–S

Reader Aids

Federal Register

Vol. 72, No. 74

Wednesday, April 18, 2007

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives. gov/federal__register**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, APRIL

15597–15804 2
15805–16260 3
16261–16694 4
16695–16984 5
16985–17352 6
17353–17788 9
17789–18102 10
18103–18342 11
18343–18560 12
18561–18846 13
18847–19092 16
19093–19374 17
19375–19660 18

CFR PARTS AFFECTED DURING APRIL

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
8119 16255
8120 17785
8121 17787
8122 18341
8123 19087
8124 19089
8125 19091

Executive Orders:
13417 (See 13429) 18101
13429 18101

Administrative Orders:
Memorandums:
Memorandum of June 2, 2005 (See Memo. of April 10, 2007) 18561
Memorandum of December 16, 2005 (See Memo. of April 10, 2007) 18561
Memorandum of March 23, 2007 18103
Memorandum of April 10, 2007 18561
Notices:
Notice of March 30, 2007 15803
Notice of April 1, 2007 16259

5 CFR

550 19093
890 19099
2634 16985
2635 16985
2636 16985
3201 19375

Proposed Rules:
1820 18406
9501 19126

6 CFR

27 17688
Ch. X 17789

7 CFR

301 15597
319 15805
762 17353
915 16261
916 18847
917 18847
922 16263
926 16265
932 18343
946 17792
959 17360
985 18345
989 17362
1207 16267

Proposed Rules:
925 18922
959 17037
3560 16730

8 CFR

103 19100
204 19100
214 .....18856, 19100
245 19100
245a 19100

9 CFR

105 17795
115 17795
202 19108

Proposed Rules:
1 17814

10 CFR

72 19109
300 15598
490 18860

Proposed Rules:
50 16731
73 17440

11 CFR

104 16695
111 16695

12 CFR

4 17798
204 16987
208 17798
211 17798
337 17798
347 17798
563 17798
563e 19109
611 16699
612 16699
614 16699
615 16699
618 16699
619 16699
620 16699
630 16699
652 15812
655 15812
915 15600

Proposed Rules:
40 16875
216 16875
332 16875
573 16875
716 16875
915 15627

13 CFR

102 17367
120 18349

14 CFR

25 .....18365, 18372, 18861

39 .....15603, 15812, 15814, 15816, 15818, 15820, 15822, 16699, 16701, 16703, 16990, 16998, 17376, 17379, 18375, 18377, 18380, 18563, 18565, 18566, 18862, 19110, 19380
61 18556
63 18556
65 18556
71 .....15824, 15825, 16707, 16708, 16709, 16710, 17804, 18383, 18568
91 .....16710, 19382
95 18384
97 .....15825, 18865, 18867
136 19382
187 18556
331 17381
401 17001
404 17001
405 17001
406 17001
413 17001
415 17001
420 17001
431 17001
437 17001

Proposed Rules:
23 18136
25 .....17441, 18136, 18412, 18597, 18923
33 .....18136, 18148
35 18136
39 .....15633, 15635, 15850, 16287, 16289, 16741, 16744, 16747, 16749, 17042, 17045, 17443, 18155, 18413, 18415, 18598, 18600, 18925
61 18092
65 18092
67 18092
71 17445
183 18092

15 CFR

19 18869
21 18869
22 18869
303 16712
902 18105

16 CFR

Proposed Rules:
313 16875

17 CFR

30 17989
140 16269
145 16269
200 16934
232 16934
240 16934
249 16934

Proposed Rules:
1 .....15637, 18316
3 .....15637, 18316
4 .....15637, 18316
15 .....15637, 18316
160 16875
166 .....15637, 18316
248 16875

18 CFR

35 .....18569, 18880, 19112
37 .....18569, 18880, 19112
40 16416
101 .....16716, 17393
381 19116
388 18572
1310 18118

19 CFR

123 18574

20 CFR

404 16720
416 16720

21 CFR

179 17394
520 16270
524 18118
558 16270
803 17397
814 17397
820 17397
821 17397
822 17397
866 15828
874 17397
886 17397
1002 17397
1005 17397
1020 17397
1300 17401
1313 17401

Proposed Rules:
179 16291

22 CFR

126 15830

23 CFR

Proposed Rules:
637 17447

24 CFR

92 16678
115 19070
234 16688

26 CFR

1 .....16878, 17804, 18386, 18575, 19234
11 16878

Proposed Rules:
1 .....17814, 18417

28 CFR

500 16271
501 16271

29 CFR

4022 18576
4044 18576

Proposed Rules:
570 .....19328, 19337
1910 18792

30 CFR

250 18577
938 19117

Proposed Rules:
291 17047
946 .....17449, 17452

31 CFR

82 18880
538 15831
560 15831

32 CFR

310 18758
706 18119

Proposed Rules:
112 19136
199 18927
213 19411
232 18157

33 CFR

100 .....15832, 17024, 18120, 18122
117 .....18884, 18885, 18887
160 17409
165 .....15834, 15837, 16275, 16726, 17024, 18124, 18126, 18585, 18887, 18889

Proposed Rules:
100 .....17062, 17456, 18170, 18422, 18424
117 .....15852, 16752, 17065
147 18929
165 .....16754, 17458, 18172, 18174, 18176, 18931, 18933, 18935

34 CFR

200 17748
300 17748

36 CFR

Proposed Rules:
261 15641
1192 18179

37 CFR

1 18892
2 18907
7 18907
41 18892

Proposed Rules:
202 16306
381 19138

38 CFR

4 16728
17 18128
21 .....16962, 19383

39 CFR

20 16604
111 18388

Proposed Rules:
111 18179

40 CFR

52 .....15839, 18389, 18391, 18394, 19383
62 17025
63 19385
65 19385
174 16277
180 .....16281, 18128
261 17027

Proposed Rules:
52 .....17461, 18426, 18427, 18428, 18434, 18602, 19144, 19413, 19424, 19435
62 17068
63 .....16636, 19150
81 .....18434, 18602, 19413, 19424, 19435
92 15938
94 15938
152 .....16312, 18191
156 .....16312, 18191
167 .....16312, 18191
168 .....16312, 18191
169 .....16312, 18191
172 .....16312, 18191
174 .....16312, 18191, 19590, 19640
180 17068
1033 15938
1039 15938
1042 15938
1065 15938
1068 15938

41 CFR

302-17 17410

Proposed Rules:
102-38 15854

42 CFR

405 18909
410 18909
411 .....17992, 18909
414 .....17992, 18909
415 18909
424 18909

43 CFR

Proposed Rules:
10 18192

44 CFR

65 18587
67 .....17413, 17426

Proposed Rules:
67 17463

46 CFR

501 15613

47 CFR

73 .....16283, 19387
90 19387
301 18400

Proposed Rules:
73 .....16315, 19447
76 19448

48 CFR

1523 18401
1552 18401

49 CFR

23 15614
26 15614
211 17433
571 17236
585 17236
801 18914
1002 17032

Proposed Rules:
39 18614
107 18446
171 18446
172 18446
173 18446
176 18446
178 18446
180 18446
385 18615
386 18615
390 18615
392 18615
393 18615
396 18615
544 17465
1300 16316

1313.....16316

50 CFR

17.....16284, 18518
92.....18318
270.....18105
300.....18404, 19122
622 .....15617, 18134, 18593
648 .....17806, 17807, 18594
660.....19390
665.....19123
679 .....15848, 18135, 18595, 18920

Proposed Rules:

17.....15857, 16756
20.....18328
223.....18616
224.....18616
300.....17071
635.....16318
648 .....17076, 17085, 18193, 18937, 18940
660.....17469, 19453
679.....18943, 19454

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT APRIL 18, 2007

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Caribbean, Gulf, and South Atlantic fisheries—
Tilefish; published 4-13-07

HOMELAND SECURITY DEPARTMENT
Coast Guard
Drawbridge operations:
Michigan; published 3-28-07

NUCLEAR REGULATORY COMMISSION
Plants and materials; physical protection:
Design basis threat; published 3-19-07

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Boeing; published 4-3-07
Gulfstream; published 4-3-07
Honeywell Flight Management Systems; published 4-3-07

TREASURY DEPARTMENT
Currency and foreign transactions; financial reporting and recordkeeping requirements:
Bank Secrecy Act; implementation—
Banco Delta Asia and subsidiary; special measure imposition as primary money laundering concern financial institution; published 3-19-07

VETERANS AFFAIRS DEPARTMENT
Vocational rehabilitation and education:
Montgomery GI Bill-Active Duty entitlement; transfer to dependents option; published 4-18-07

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Food Safety and Inspection Service
Meat and poultry inspection:
Poultry product exportation to United States; eligible countries; addition—
Chile; comments due by 4-27-07; published 2-26-07 [FR E7-03155]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
West Coast States and Western Pacific fisheries—
Coastal pelagic species; comments due by 4-27-07; published 2-26-07 [FR E7-03247]
Pacific Coast groundfish; comments due by 4-24-07; published 4-9-07 [FR E7-06643]
International fishing regulations:
Pacific halibut—
Guided sport charter vessel fishing; harvest restrictions; comments due by 4-23-07; published 4-6-07 [FR E7-06422]

COMMODITY FUTURES TRADING COMMISSION
Commodity Exchange Act:
Designated contract markets; conflicts of interest in self regulation and self-regulatory organizations; acceptable practices; comments due by 4-25-07; published 3-26-07 [FR E7-05468]

ENVIRONMENTAL PROTECTION AGENCY
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
Arizona; comments due by 4-27-07; published 3-28-07 [FR E7-05663]
Air quality implementation plans; approval and promulgation; various States:
Arizona and California; comments due by 4-23-07; published 3-23-07 [FR E7-05357]
Illinois; comments due by 4-23-07; published 3-23-07 [FR E7-05360]
Wisconsin; public hearings; comments due by 4-27-07; published 2-23-07 [FR 07-00826]
Hazardous waste program authorizations:
New York; comments due by 4-25-07; published 3-26-07 [FR 07-01454]
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Pesticide treated food packaging; comments due by 4-23-07; published 4-6-07 [FR E7-06349]

FEDERAL COMMUNICATIONS COMMISSION
Practice and procedure:
Antenna structures; construction, marking, and lighting—
Communications towers effect on migratory birds; comments due by 4-23-07; published 1-26-07 [FR E7-01190]
Radio stations; table of assignments:
Oregon; comments due by 4-23-07; published 3-21-07 [FR E7-05073]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Food for human consumption:
Food labeling—
Gluten-free; voluntary nutrition labeling; comments due by 4-23-07; published 1-23-07 [FR E7-00843]
Health claims; soluble fiber from certain foods and risk of coronary heart disease; comments due by 4-23-07; published 2-6-07 [FR E7-01849]

HOMELAND SECURITY DEPARTMENT
Coast Guard
Great Lakes pilotage regulations:
Rate adjustments; comments due by 4-24-07; published 2-23-07 [FR E7-03061]
Transportation Worker Identification Credential Program; maritime sector implementation:
Merchant mariner qualification credentials consolidation; comments due by 4-25-07; published 1-25-07 [FR 07-00018]

INTERIOR DEPARTMENT
Land Management Bureau
Minerals management:
Mining claims under general mining laws; surface management; comments due by 4-24-07; published 2-23-07 [FR E7-03077]

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species:
Findings on petitions, etc.—
Utah Prairie Dog; reclassification and 5-year review; comments due by 4-23-07; published 2-21-07 [FR E7-02834]
Virginia northern flying squirrel; delisting; comments due by 4-23-07; published 2-21-07 [FR 07-00787]
Correction; comments due by 4-23-07; published 3-6-07 [FR 07-00855]
Migratory bird permits:
Resident Canada goose populations; management; comments due by 4-23-07; published 3-22-07 [FR E7-05199]

JUSTICE DEPARTMENT
Executive Office for Immigration Review
Immigration:
Jurisdiction and venue in removal proceedings; comments due by 4-27-07; published 3-28-07 [FR E7-05629]

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
Public availability and use:
Reproduction services; fee schedule; comments due by 4-27-07; published 2-26-07 [FR E7-03160]

NUCLEAR REGULATORY COMMISSION
Nuclear Materials Management and Safeguards System; regulatory improvements; comments due by 4-23-07; published 2-6-07 [FR E7-01867]

PENSION BENEFIT GUARANTY CORPORATION
Premium payments:
Distress and involuntary plan terminations; flat premium rates, variable-rate premium cap, and termination premium; comments due by 4-23-07; published 2-20-07 [FR E7-02812]

POSTAL SERVICE
Domestic Mail Manual:
Periodicals mailing services; new standards; comments due by 4-25-07; published 4-11-07 [FR 07-01796]

TRANSPORTATION DEPARTMENT
Individuals with disabilities:
Passenger vessels; accessibility guidelines; comments due by 4-23-07; published 1-23-07 [FR E7-00362]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Airbus; comments due by 4-23-07; published 3-29-07 [FR E7-05666]
APEX Aircraft; comments due by 4-23-07; published 3-23-07 [FR E7-05226]
BAE Systems (Operations) Ltd.; comments due by 4-27-07; published 3-28-07 [FR E7-05650]
Boeing; comments due by 4-24-07; published 3-30-07 [FR E7-05928]
Empresa Brasileira de Aeronautica S.A. (EMBRAER); comments due by 4-24-07; published 3-30-07 [FR E7-05911]
Superior Air Parts, Inc.; comments due by 4-24-07; published 2-23-07 [FR E7-02985]
Viking Air Ltd.; comments due by 4-23-07; published 3-22-07 [FR E7-05215]
Airworthiness standards:
Special conditions—
Boeing Model 787-8 airplane; comments due by 4-26-07; published 3-12-07 [FR E7-04306]
Class E airspace; comments due by 4-26-07; published 3-12-07 [FR 07-01127]
Offshore airspace areas; comments due by 4-27-07; published 3-13-07 [FR E7-04466]

TRANSPORTATION DEPARTMENT
Federal Transit Administration
National transit database uniform system of accounts and reporting system:
Nonurbanized area formula grants recipients; reporting and recordkeeping requirements; comments due by 4-25-07; published 3-26-07 [FR E7-05417]

TREASURY DEPARTMENT
Internal Revenue Service
Income taxes:
Unified rule for loss on subsidiary stock; comments due by 4-23-07; published 1-23-07 [FR 07-00187]

TREASURY DEPARTMENT
Thrift Supervision Office
Savings and loan holding companies:
Permissible activities; comments due by 4-26-07; published 3-27-07 [FR E7-05453]

TREASURY DEPARTMENT
Alcohol and Tobacco Tax and Trade Bureau
Alcohol; viticultural area designations:
Paso Robles Westside, San Luis Obispo County, CA; comments due by 4-24-07; published 3-23-07 [FR E7-05353]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

S. 494/P.L. 110–17

NATO Freedom Consolidation Act of 2007 (Apr. 9, 2007; 121 Stat. 73)

Last List March 30, 2007

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.